People’s experiences living with achalasia: new insights into long-term management

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Abstract:

Background: Achalasia is a rare, chronic condition that affects the motility of the oesophagus and significantly impacts the lives of people affected. Recognising the importance of understanding the lived experience, this thesis sets out to identify the challenges faced by people living with achalasia and collaboratively develop a potential solution for improved long-term management.

Methods: The thesis utilised a mixed-method approach across three distinct studies, incorporating process mapping, intervention co-design, and a feasibility study. The first study collected qualitative data from process mapping sessions, detailing the experiences and challenges faced by people living with achalasia and identifying key areas for support. The second study focussed on the primary challenge prioritised by participants. A series of online focus groups were conducted to provide a comprehensive analysis of this challenge, facilitating collaborative discussions around potential intervention strategies. Building on the insights gathered from these focus group discussions, an intervention was co-designed to meet the identified need. The thesis concludes with a mixed-method feasibility assessment, utilising questionnaires and semi-structured interviews to measure the acceptability, usability, and potential efficacy of the proposed intervention.

Results: In addition to the clear physical problems, achalasia also brings about hidden social challenges that people living with achalasia face in their everyday lives. In study 1, a process map was developed to detail the lived experiences of people living with achalasia from diagnosis to long-term management. One of the predominant challenges consistently identified was issues related to eating behaviour, evident at every stage of their journey with achalasia. Informed by these insights, participants in study 2 specifically identified "eating in social settings" as a target behaviour for intervention. Using the COM-B model as a framework, the behaviour change intervention was co-designed, and an evidence-based workbook was developed. Testing the feasibility and practicality of this workbook, implemented in a real-world setting, was the focus of study 3. This feasibility study provided insight into participant recruitment and retention. Positive feedback on the workbook's usability was a key finding, along with the potential effectiveness in supporting people living with achalasia. Participants reported that the significant strength of the workbook was its content alignment with their unique experiences and challenges.

Conclusion: In conclusion, this thesis has illuminated the intricacies of living with achalasia, offering insights into the experiences of individuals facing this rare condition. Through a patient-centric approach and by co-designing an intervention specifically targeting the challenge of social eating, this thesis demonstrates the principles of patient-centred care. The feasibility study indicated the intervention's

potential effectiveness. The application of these findings lies in the real-world impact of the co-designed intervention, which has the potential to significantly improve the lives of those living with achalasia by addressing a critical aspect of their daily challenges including social eating. Subsequent research should focus on assessing the sustained efficacy of this intervention and advocate for the continued inclusion of patient perspectives in shaping more comprehensive and impactful solutions for individuals living with rare chronic conditions like achalasia.

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Acknowledgement

To my dearest parents, Azita and Mohammad Mahdi, words fall short to express my deep gratitude for your relentless support. You have been my anchor in the most turbulent of times and my guiding star leading me towards my aspirations. Your sacrifices, often unseen but always felt, have been the foundation upon which my academic achievements stand. From my earliest steps on the path of education, you instilled in me a love for learning and the courage to ask questions, shaping me into the researcher I am today. Your faith in my abilities, even when faced with adversity, has been my source of strength, inspiring me to persevere. The lessons I have learned from your wisdom and the values you have upheld, resilience in the face of challenges and the importance of hard work are the guiding principles that have directed my journey. Your unconditional love and encouragement have nurtured not just my academic ambitions but also my personal growth. You taught me to value integrity over success and compassion over competition. These lessons have not only made me a better researcher but also a better person. For your love, guidance, and endless support, I am profoundly grateful. This accomplishment is as much yours as it is mine. My brother, Amir Ali, deserves a special mention for the joy he brings into my life. His humour and enthusiasm have been a constant source of relief during the most stressful times. His presence and spirit have contributed immensely in keeping me grounded and focused.

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Declaration

I, Melika Kalantari, confirm that this is my own work and the use of all material from other sources has been properly and fully acknowledged.

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Dissemination of findings

Research publication

1. Kalantari M, Hollywood A, Lim R, Hashemi M. Mapping the experiences of people with achalasia from initial symptoms to long-term management. Health Expectations. 2021;24:131–139. https://doi.org/10.1111/hex.13160
2. Kalantari M, Hollywood A, Lim R, Hashemi M. Co-designing an intervention using the COM-B model to change an eating behaviour in people living with achalasia. Frontiers. (Resubmitted to Gastrointestinal Autonomic Disorders in Frontiers in Neurology, section Autonomic Disorders in January 2024, and it is under review)
3. Kalantari M, Hollywood A, Lim R, Hashemi M. A co-designed intervention to support people living with achalasia to eat in a social setting: a feasibility study (Submitted to BMC Pilot and Feasibility studies in November 2023, and it is under review)

Conference presentations

1. Kalantari, M. Hollywood, A, Lim, R. & Hashemi, M. Co-designing a behaviour change intervention using COM-B for people living with achalasia. Health Services Research 5-7th July 2022, Sheffield, UK
2. Kalantari, M. Hollywood, A, Lim, R. & Hashemi, M. Mapping the journey of people with achalasia. Health Services Research & Pharmacy Practice conference 16-17th April 2020, Virtual conference
3. Kalantari, M. Hollywood, A, Lim, R. & Hashemi, M. Co-designing an intervention to change eating behaviour in people living with achalasia. Pharmacy virtual PhD conference 2nd-3rd July 2020, Reading, UK
4. Kalantari, M. Hollywood, A, Lim, R. & Hashemi, M. Process mapping the journey of people with achalasia. Pharmacy PhD conference, 11th April 2019, Reading, UK

Relevant training

1. Focus Groups in Qualitative Research – Theory and Practice. February 2020, University College London. UK
2. Understanding Qualitative Research Method. January 2020, University College London. UK
3. Quality assurance in research. December 2019. University of Reading, UK.
4. How to Stop Procrastinating (or The Secret to Getting Started). December 2019, University of Reading, UK.
5. EBCD: Experience-based co-design. November 2019, The Point of care foundation, London, UK
6. Managing data & research material. November 2019. University of Reading, UK.
7. Creative Thinking and Problem-Solving. November 2018, University of Reading, UK.
8. Self-Management: Increasing concentration. November 2018, University of Reading, UK.
9. Doctoral Research Conference. June 2018, University of Reading, UK.
10. Sourcing information for a literature review – information retrieval. February 2018, University of Reading, UK.
11. An Essential Guide to Critical Academic Writing. February 2018, University of Reading, UK.

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Abbreviations

BCW	Behaviour Change Wheel
COM-B	Capability-Opportunity-Motivation-Behaviour
COPD	Chronic obstructive pulmonary disease
HM	Heller Myotomy
HRM	High-resolution manometry
HRQoL	Health-Related Quality of Life
IMB	Information-Motivation-Behavioural-Skills Model
LOS	Lower oesophageal sphincter
MMR	Mixed Method Research
PAR	Participatory action research
PBS	Painful Bladder Syndrome
PD	Pneumatic dilatation
POEM	Peroral endoscopic myotomy
SCT	Social Cognitive Theory
TPB	Theory of Planned Behaviour
TTM	Transtheoretical Model of Change
UK	United Kingdom

Chapter 1

1.1 Introduction

1.1.1 Background

Achalasia is a rare motility disorder affecting the oesophagus. It is a disorder of the enteric nervous system characterised by loss of neurons leading to the absence of peristalsis and impaired relaxation of the lower oesophageal sphincter. (1) It was first described in the 17th century by Thomas Willis. Achalasia is a Greek term which means “non-relaxing” or “failure to relax”. It is a chronic condition, and it does not have a cure. Achalasia is not a common medical disorder; therefore, most clinicians will not encounter a patient in their everyday practice. (2) Although it is rare, achalasia is one of the most studied oesophageal motility disorders(3), with research primarily focusing on various aspects of the condition’s aetiology, diagnosis, symptomatology and medical or surgical treatment options.

1.1.2 Aetiology

While the exact cause of achalasia remains poorly understood (4) , it has been attributed to the deterioration of the myenteric plexus and vagus nerve fibres that innervate the lower oesophageal sphincter. (5) However, the exact aetiology of achalasia and the degeneration of the nerve fibres are unclear. There have been many proposed theories, including viral infection, genetic predisposition and an autoimmune phenomenon. (5)

1.1.3 Epidemiology

Achalasia affects individuals regardless of their race, age, or biological sex, showing equal frequency among both women and men(6) It can manifest at any stage in life, yet it predominantly affects individuals between their twenties and fifties, with a peak incidence between the ages of 30 to 60 years. (5)

1.1.4 Clinical presentation

Achalasia is a progressive disease that presents with different symptoms. The diagnosis of achalasia should be suspected when any patient presents with dysphagia for both liquids and solids. Patients can also have regurgitation, chest pain, heartburn and weight loss. There are often delayed diagnoses due to the similarities of symptoms with gastro-oesophageal reflux disease. Other symptoms of achalasia not only include slow eating (achalasia patients often report being the last ones to finish their meals when asked, and they may mention teasing from family or friends to eat faster) (6) but also post-meal physical movements such as stretching, moving from side to side, or walking around after meals to help the food pass through the blocked oesophagus and lower oesophageal sphincter. (6) There is a gradual onset of dysphagia in patients. Most patients initially describe that as a “sticking sensation” or “fullness in the chest”, which occurs daily after every meal. (2) Regurgitation can become problematic as the disease progresses and the oesophagus dilates. Bringing up undigested food can keep patients awake at night because of coughing and choking. These symptoms often lead to misdiagnosis of achalasia to postnasal phlegm or bronchitis. (2)

1.2 Diagnosis

1.2.1 Diagnostic testing

Achalasia is often subject to delayed diagnosis, primarily because it is not recognised as a distinct condition and is instead mistaken for a more common disease, such as gastro-oesophageal reflux disease. Diagnosis is typically delayed up to 2 to 3 years from the onset of symptoms. (6) There are different diagnostic tests available to diagnose achalasia. Endoscopy, barium esophagram and oesophageal manometry are the three established and often complementary tests in diagnosing achalasia. (3)

1.2.1.1 Endoscopy

An endoscopy is a procedure where the doctor uses a device called an endoscope, a flexible tube with a light and camera attached to it, to visualise the inner lining of the digestive tract. Assessments of oesophageal peristalsis and lower oesophageal sphincter (LOS) functionality during an upper gastrointestinal endoscopy are not always precise; however, the presence of undigested food retained in the oesophagus could be a more specific indicator for achalasia diagnosis.

1.2.1.2 Barium esophagram

A barium esophagram also known as a barium swallow, is a diagnostic imaging test used to evaluate the structure and function of the oesophagus. It is a very established test in the diagnosis of achalasia. The findings from the radiograph show the smooth tapering in the distal oesophagus with the typical “bird’s beak” appearance. (see Figure 1) (6)

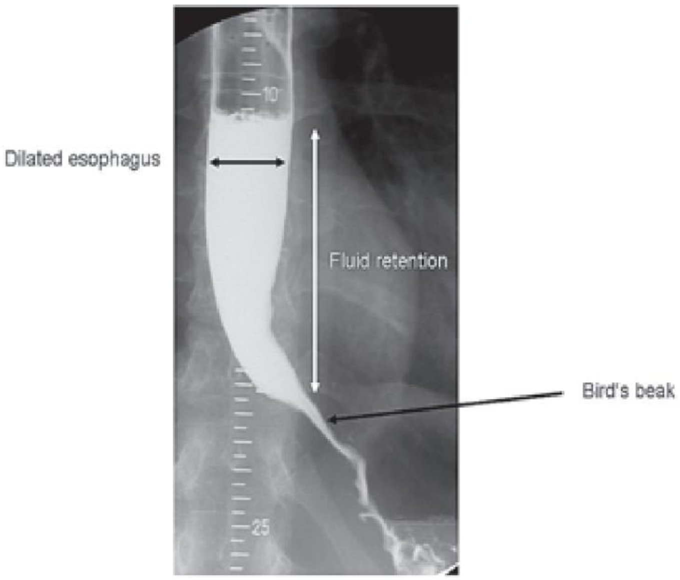

Figure 1. Barium esophagram in achalasia. (6)

1.2.1.3 Manometry

Oesophageal manometry which is a diagnostic test used to evaluate the function and motility of the oesophagus is the gold standard in diagnosing achalasia. (6) The absence of peristalsis, along with increased intraoesophageal pressure due to accumulation of food and saliva and incomplete relaxation of the lower oesophageal sphincter (LOS), are the hallmarks of achalasia. (7) High-resolution manometry (HRM) provides more detailed information on oesophageal motility. Over the years, the data collected by HRM has led to the development of the Chicago classification scheme, which classifies achalasia into three subtypes I, II, and III (see Figure 2.). (4) In type I, there are no oesophageal contractions which means the oesophagus has lost its ability to contract, making it hard for food to pass from the oesophagus to the stomach. In type II there is simultaneous pressurisation which means that the muscle contractions occur at the same time along the length of the oesophagus instead of in a wave-like motion from the top to bottom, which would normally push food down to the stomach, and in type III high-pressure non-peristaltic body contraction that do not follow the normal wave-like motion (non-peristaltic). These are strong, uncoordinated contractions that can cause pain, trouble swallowing, or food getting stuck in the oesophagus. (4) In order to ensure optimal patient outcomes, it is crucial to correctly diagnose the type of achalasia and choose the appropriate treatment and management for the people living with achalasia.

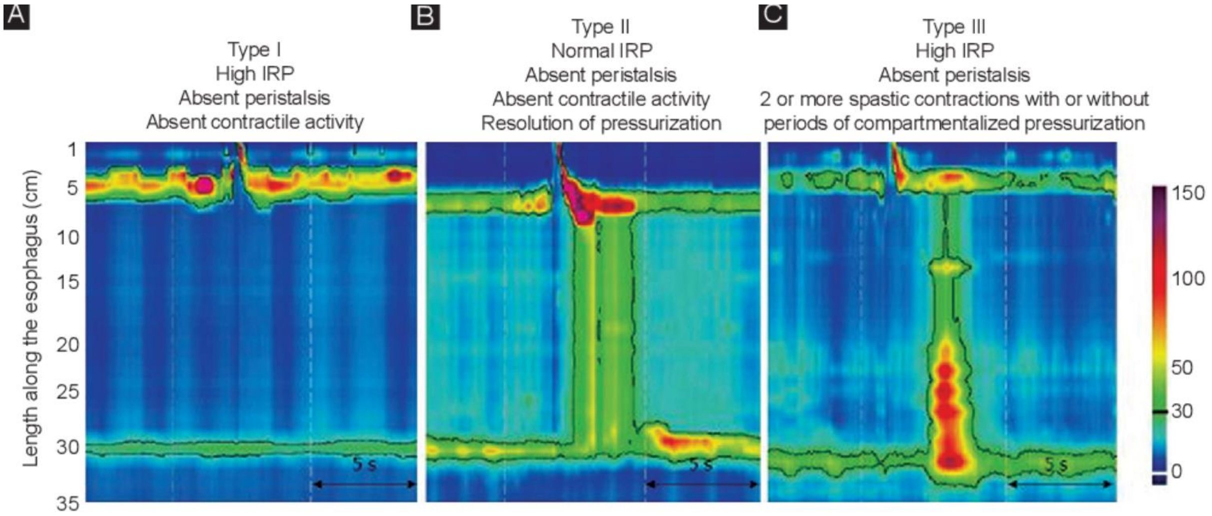

Figure 2: High-resolution oesophageal pressure manometry depicting the three distinct types of achalasia. (4)

1.2.2 Severity assessment

In managing achalasia, evaluating the severity of symptoms is crucial and this is effectively done using the Eckardt symptom score. This score ties into the clinical staging of achalasia, which in turn influences the course of treatment. Clinical stages, based on disease severity, align with the Eckardt score that grades symptoms of weight loss, chest pain, dysphagia, and regurgitation. Before introducing the Eckardt symptom score, it is important to clarify the concept of clinical stages in achalasia. Clinical stages are relevant to all types of treatment for achalasia. These stages represent different levels of disease severity. A score of 0-1 corresponds to clinical stage 0, 2-3 to stage I, 4-6 to stage II, and a score higher than 6 to stage III (see Table 1). In stage 0, individuals who have undergone treatment and show no symptoms are considered to be in remission. Stage I is characterised by mild symptoms, while stage II indicates moderate symptoms. Stage III represents severe symptoms and is considered a sign of treatment failure. (8)

Table 1 Eckardt score: clinical scoring for achalasia

Score	Dysphagia	Regurgitation	Retrosternal pain	Weight loss (KG)
0	None	None	None	None
1	Occasional	Occasional	Occasional	< 5
2	Daily	Daily	Daily	5-10
3	Each meal	Each meal	Each meal	> 10

1.2.3 Making a diagnosis

In the preliminary clinical assessment, a healthcare professional will evaluate the patient’s indications, including dysphagia, regurgitation, chest discomfort, and weight reduction. It is important to distinguish achalasia from other illnesses, such as gastroesophageal reflux disease (GORD) or oesophageal cancer, that could exhibit symptoms that are similar to those of achalasia. The process of diagnosing achalasia is followed by targeted diagnostic procedures, including oesophageal manometry, upper gastrointestinal endoscopy, and imaging modalities such as barium swallow. The administration of these tests aids in distinguishing achalasia from alternative medical conditions and provides significant insights for formulating a suitable course of treatment. (3)

Figure 3 presents a treatment algorithm which is created by a group of experts specifically tailored for people living with achalasia who have not undergone any previous therapy. (3) The choice of therapeutic modalities is dependent upon the various manometric subtypes of achalasia, patient preferences, and the level of expertise accessible within the healthcare organisation.

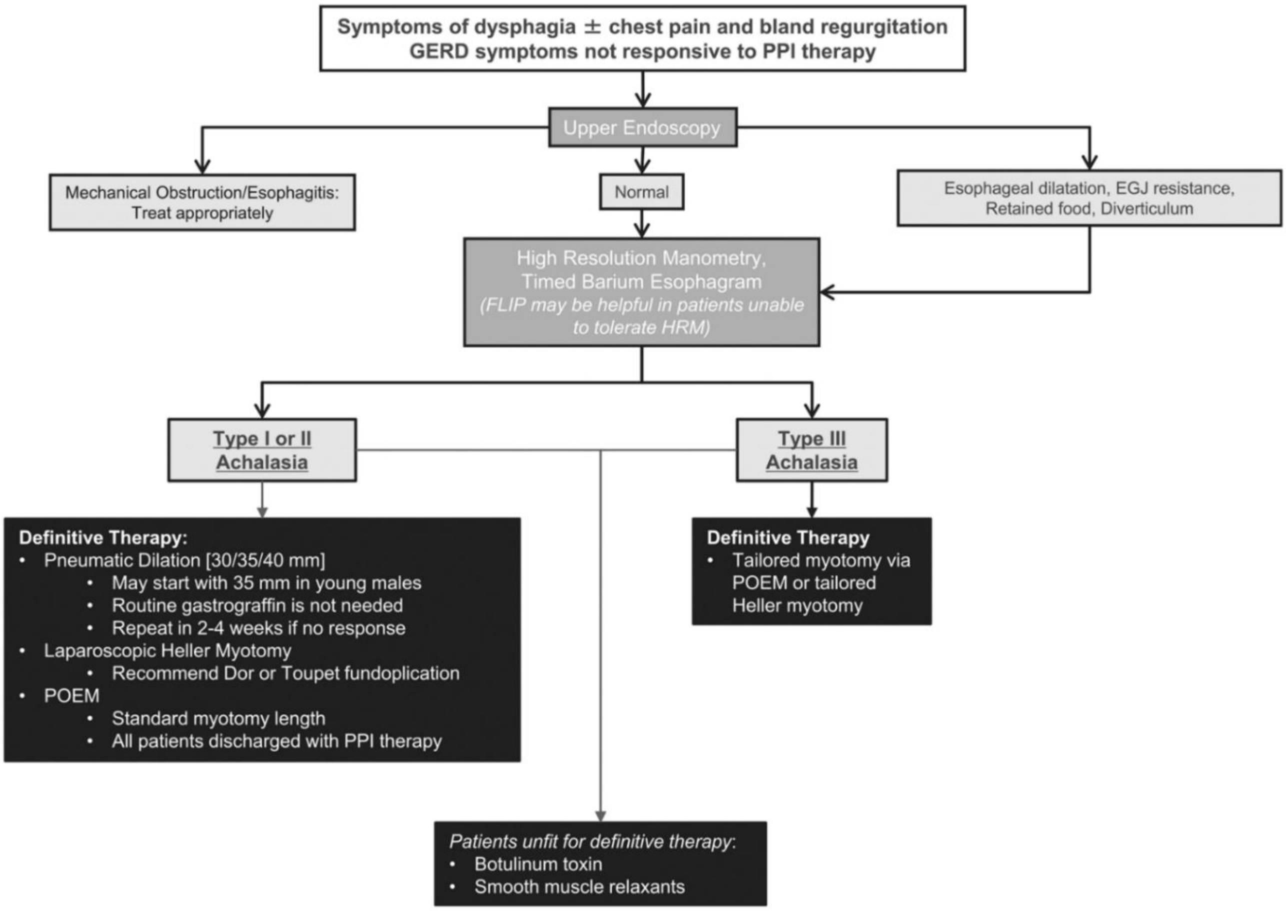

Figure 3. Algorithm for diagnosis and treatment in patients suspected of achalasia (3)

1.3 Treatment options for achalasia

There are no treatments available to restore muscular activity to the denervated oesophagus in achalasia. The aims of the current available treatments are 1) relieving patients' symptoms, 2) improving oesophageal emptying, and 3) preventing the development of megaoesophagus (an abnormal enlargement or dilatation of the oesophagus due to a lack of normal muscular function). (2) There are non-surgical and surgical treatments available for achalasia. These include oral pharmacotherapy, endoscopic botulinum toxin injection, pneumatic dilatation (see figure 4), laparoscopic Heller myotomy (LHM) and peroral endoscopic myotomy (POEM).

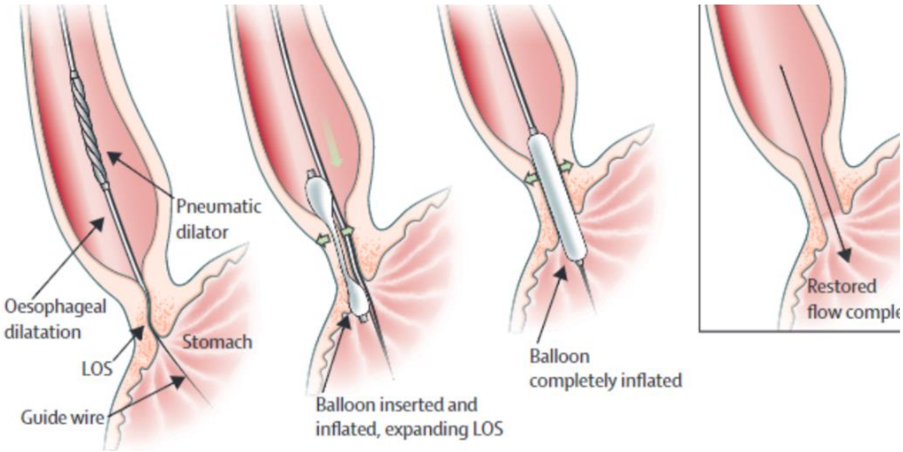

Figure 4. Endoscopic Pneumatic dilatation (7)

Each treatment has its advantages and disadvantages. Table 2 provides a comparison of the advantages and disadvantages of different achalasia treatments, including Botox injection, pneumatic dilatations, laparoscopic Heller myotomy, and POEM. Each treatment option is evaluated based on its specific advantages and disadvantages, helping to inform treatment decisions for patients with achalasia. (4)

Table 2: Comparison of Advantages and Disadvantages of Achalasia Treatments

Procedure	Advantages	Disadvantages
Botox	• Easy to perform • No need for general anaesthesia • Low complication rate • Minimally invasive, ideal for at risk patients	• Short term results • Efficacy will reduce with time • Can affect further treatments such as myotomy.
Pneumatic dilatations	• Widely available	• Repeated procedure is required in 25% of cases

	• No need for general anaesthesia • Relatively safe with less than 5% risk of perforation • No interference with other treatments (LHM/POEM)	• Post-procedural GORD can be experienced by up to 30% of cases • Less effective in patient < 40 years old
Laparoscopic Heller myotomy	• Feasible for all achalasia subtypes and stages • Feasible for treatment of failed previous myotomy • Promising outcomes over an extended duration	• Requires general anaesthesia • Post-op reflux in 10-20% of patients • Leaves small scars
POEM	• Feasible for all achalasia subtypes and stages • Feasible for treatment of failed previous myotomy • No scars	• Requires general anaesthesia • Post-op reflux in 50% of patients • Requires a skilled endoscopist

1.3.1 Non-surgical treatments

1.3.1.1 Oral pharmacotherapy

Pharmacological treatments such as calcium channel blockers, nitrates and phosphodiesterase inhibitors aim to reduce the pressure in the LOS. They are the least effective treatment option for achalasia. They only provide short-term relief of symptoms and are mainly used for patients who are waiting for surgical treatment or refused more invasive therapies such as pneumatic dilatation. (5) Nifedipine (calcium channel blocker) 10-30mg sublingual before meals and isosorbide dinitrate (nitrates) 5mg before meals are the two most common medications used to treat achalasia. They work by releasing nitrous oxide in and reducing the intracellular calcium, which can lead to the relaxation of the LOS. (3) Hypotension, headache, dizziness, oedema, the rapid development of tolerance and incomplete symptom improvement are the side-effects of these treatments. (2,3,5)

1.3.1.2 Endoscopic pharmacotherapy

Botulinum toxin injection (Botox) injection is a more widely used pharmacological treatment. It is a neurotoxin that blocks the release of acetylcholine from the nerve terminals. (7) Botox is a safe and effective treatment with few side-effects; therefore, it can be used in high-risk patients. (5) 80-100 units will be injected in four or eight quadrants into the LOS during upper-gastrointestinal endoscopy. The advantage of this treatment is the low risk of perforation and lower risk of morbidity and mortality compared to dilatation or surgical interventions. However, the response fades rapidly but can be repeated when the effects wear off. The average duration of the effect of Botox is 6-12 months in most patients. (6) As the effect of Botox is short-lived, patients often require multiple treatments that are costly and may reduce the success of subsequent surgical myotomy (a procedure that involves an incision or division of the muscle). (8)

1.3.1.3 Pneumatic Dilatation

Pneumatic dilatation (PD) via endoscopy is the most effective non-surgical treatment for achalasia. (9) It aims at disrupting the LOS by forceful dilatation using air filled balloons (see Figure 4). (2) Symptoms of achalasia improve in 50% to 93% of patients, and symptoms recurrence happen in 30% of patients after 5 years. (10) The dilators come in 3 sizes (3.0, 3.5 and 4.0 cm) and are used in a graded fashion, starting with the 3.0 cm first, followed by 3.5 cm and the 4.0 cm. The failure rate of PD is higher in the male gender, younger age (<40 years), those with pulmonary complications or those who failed one or more previous PD. (11) There is a 3% to 6% risk of oesophageal perforation with PD, which is the major reason why PD remains controversial in terms of acceptance. However, most of the perforations occurring during PD can be treated. (12,13)

1.3.2 Surgical treatments

1.3.2.1 Laparoscopic Heller Myotomy (LHM)

Heller Myotomy (HM) is a minimally invasive procedure that aims to relieve the obstruction caused by LOS. (14) It was the first successful surgery for achalasia performed in 1913 by German surgeon Ernest Heller. (15) To have a good therapeutic outcome, the myotomy has to be extended 6-7 cm above the gastro-oesophageal junction and 3 cm distally to cut the gastric sling fibres involved in the functional formation for the LOS. (16) This approach commonly lead to gastro-oesophageal reflux in many patients. Therefore, most surgeons combine the LHM with an anti-reflux procedure. (6) Postoperative gastro-oesophageal reflux still occurs in 10-30% of patients. These patients will then require proton pump inhibitors (PPI) to manage the reflux. LHM combined with partial fundoplication, which involves wrapping the top part of the stomach around the lower oesophagus, is a safe procedure. The most common complication is the perforation of the oesophageal or gastric mucosa during the myotomy, which is usually identified and rectified during the procedure without any consequences. (7)

1.3.2.2 Peroral endoscopic myotomy (POEM)

While a variety of treatments exist for achalasia and demonstrate some degree of effectiveness to alleviate symptoms of achalasia, pneumatic dilatation is associated with a risk of perforation, and myotomy still needs laparoscopy and cutting through the gastro-oesophageal junction. (3) Consequently, there has been an interest in developing a new technique that incorporates an endoscopic approach. In the POEM technique, the endoscopist makes a tunnel to reach the LOS and dissects the circular muscle fibres. (7) Observational studies have indicated that around 58% of patients suffer from reflux after POEM. (17) The incidence of this phenomenon tends to be comparatively lower in patients who have undergone pneumatic dilatation.

1.3.3 Pneumatic Dilatation versus Laparoscopic Heller Myotomy (LHM) versus Peroral Endoscopic Myotomy (POEM)

There is an ongoing debate on the most effective treatment for achalasia. It is hard to make a decision on which approach to undertake because of the lack of large randomised trials. (8) Treatment in achalasia should be tailored for each individual patient. Patients with symptoms of achalasia should undergo upper endoscopy followed by high-resolution manometry and time barium swallow to confirm the diagnosis. The choice of treatment depends on the type of achalasia. People with type I and II can choose PD, LHM and POEM. Patients who are unresponsive to PD should undergo LHM. In patients with type III achalasia, LHM or POEM should be considered. Patients with comorbidities who cannot undergo the more invasive procedures can be offered Botox or muscle relaxants to reduce the risk of complications such as dysphagia and perforation. Regardless of the type of treatment, all patients should be followed up for symptoms recurrence and complications that can arise from different treatments. Figure 3, located under section 2 "Diagnosis" and subsection 2.3 "Making a Diagnosis," shows the algorithm for diagnosing and treating patients with suspected achalasia. (3)

1.4 Background literature on achalasia

In the field of achalasia research, the existing body of knowledge predominantly focuses on the classification of achalasia types, medical interventions, and the success rates associated with different treatment options. Current studies and clinical trials have underscored the limited efficacy of pharmacological treatments, such as Botox injections, for achieving long-term symptom control. While these approaches may offer some relief, they often require periodic reinjections and may not provide sustainable benefits over time. On the other hand, the three well-established and effective medical interventions PD, LHM and POEM have emerged as leading treatment modalities. The choice of which intervention to offer often depends on local expertise and the subtype of achalasia. (18)

Moreover, the current literature has made significant strides in understanding the pathogenesis of achalasia and evaluating various treatment options, along with their respective success rates. (19) However, it is important to note that a visible gap exists in the literature regarding non-medical interventions and patient experiences. The extensive review of existing research underscores that the emphasis has primarily centred on medical approaches. Non-medical interventions, encompassing lifestyle modifications, dietary management, and behavioural therapies, remain underexplored in the context of achalasia management. Additionally, insights into the experiences and perspectives of individuals living with achalasia have been notably absent.

Given the limited long-term success of some medical treatments and the variation in patient responses, there is a compelling need to explore alternative approaches beyond the medical domain and to gain a deeper understanding of the patient's journey. Non-medical interventions could offer valuable adjunctive options or even serve as primary strategies in managing achalasia, with the potential to enhance patient well-being, symptom control, and overall quality of life. As this thesis progresses, it will not only delve into the uncharted territory of non-medical interventions for achalasia but also seek to amplify the patient's voice and experience in the literature, thereby filling critical gaps and contributing novel insights to the field.

1.5 Challenges of chronic conditions

After discussing the various treatment options available for achalasia, it is important to consider the long-term implications and challenges faced by people living with this chronic condition. The effectiveness of the chosen treatment modality significantly influences the quality of life and overall management of achalasia as a chronic condition. Understanding the unique challenges and complexities associated with chronic conditions, with a specific focus on achalasia will provide valuable insights into the holistic care and support required for individuals undergoing these treatments. This section will explore the broader landscape of chronic conditions and shed light on the multifaceted challenges that people with achalasia may encounter throughout their journey of treatment and beyond. The term “chronic condition” is widely used in different professional communities such as medical, public health and academic. Various resources provide differing definitions for chronic conditions. However, in most studies, a chronic condition is defined as a long-term health condition that typically lasts for a year or more and requires ongoing medical care and management. (20,10) Examples of chronic conditions include diabetes, hypertension, asthma, arthritis, chronic obstructive pulmonary disease, heart disease, and cancer. While these chronic conditions have been extensively studied, there is a lack of knowledge about the challenges specific to achalasia, including patient’s experiences with the disease and the ongoing support that is available for them. Chronic conditions are often associated with a reduced quality of life, disability, and increased healthcare costs. Patients require ongoing monitoring and management to prevent complications and maintain optimal health. Although many chronic conditions cannot be cured, they can often be controlled through lifestyle changes, medication, and other interventions.(20,21,22) A significant emotional load might result from a chronic medical illness in adolescence. Social and emotional well-being might face significant challenges from initial stressors related to diagnosis, persistent stress from treatments and social disturbance, social stigma and isolation, and changes in plans and goals for the future. (23) The incidence of chronic illnesses is higher among individuals who are older, with 58% of individuals over the age of 60 being affected compared to only 14% of those under the age of 40. (24) Social and emotional well-being are significantly affected by challenges from initial stressors related to diagnosis, persistent stress from treatments and social disturbance, social stigma and isolation, and changes in plans and goals for the future. (25)

The prevalence of chronic diseases has also significantly affected the workforce. Compared to healthy workers, those with chronic conditions are unemployed, work fewer hours, or are less productive.(264) When chronic disease incidence rates continue to grow, the chance of experiencing decreased productivity and rising welfare costs will continue to climb. (26) Chronic disease is also a significant problem globally for healthcare systems, which have mostly evolved to provide acute episodic care rather than structured care for patients with long-term disorders. (27) In order to effectively address the challenges associated with chronic conditions such as achalasia, it is important to develop healthcare strategies that are comprehensive and patient-centred. Additionally, promoting techniques for effective management and self-management is crucial which will be discussed in the next section.

1.6 Quality of life in chronic disease

The World Health Organization (WHO) defines quality of life (QoL) as how people perceive their own life status, influenced by their cultural background and personal values. This perception is shaped in relation to their life objectives, their anticipations, the standards they have set for themselves, and the issues that matter to them. (28) Over recent years, there has been a growing prevalence and awareness of chronic illnesses, including achalasia. A significant number of individuals live with these long-term health conditions, which can negatively impact their quality of life. (29) Health-Related Quality of Life (HRQoL) in the context of achalasia is a multifaceted concept that encompasses physical, mental, and social well-being. These areas are influenced by a person's illness and/or the treatment they are undergoing. HRQoL is typically assessed in cases of chronic diseases and is often significantly diminished. (29) While studies have explored HRQoL in various chronic diseases, it is essential to delve into the specific factors affecting the QoL of individuals living with achalasia, considering the unique challenges and implications of this oesophageal motility disorder.

Devins et al. (1983) propose that chronic illnesses can cause significant disruptions in a person's life. This disruption can be understood in terms of its effects on the individual's overall well-being or their quality of life. (30) Research generally suggests that in patients with various chronic illnesses, factors such as concurrent chronic conditions, risky health behaviours, depressive signs, sleep disorders, and cognitive decline are linked to a lower Health-Related Quality of Life. Consequently, early and aggressive treatment of conditions like diabetes, obesity, and left ventricular dysfunction, along with spiritual practices and interventions aimed at reducing psychological distress, can lead to improvements in HRQoL. (29)

1.7 Management and self-management of chronic conditions

In recent decades, the frequency of chronic disease has increased rapidly, making it the leading cause of mortality worldwide. (31) In 2005, the World Health Organization projected that chronic diseases accounted for 49% of the overall global burden of disease, and this proportion was expected to be as high as 72% among those aged 30 and older. (32) The greatest difficulty most medical practices face is meeting the diverse demands of patients with chronic illnesses. According to Wagner (1998) numerous surveys and audits have consistently shown that a significant number of chronically ill patients are not receiving adequate therapy, have poor disease management, and are unsatisfied with their care. (33)

The challenges of managing chronic conditions such as achalasia go beyond medical intervention alone. Patients with chronic conditions, like achalasia, must actively engage in self-management strategies and interventions to acquire the skills necessary to live with their illness effectively. While much has been written about self-management in various chronic diseases, it is crucial to emphasise the unique aspects of self-management in the context of achalasia, where treatment options primarily aim to alleviate symptoms and often require patients to take an active role in managing their condition.

The majority, if not all, of chronic diseases, require adequate medical intervention for their management. However, it is crucial to acknowledge that the responsibility for managing chronic diseases does not solely lie with healthcare professionals or health systems. Instead, the primary responsibility lies with the patients themselves. Therefore, patients are always the centre of any chronic illness management. They can become excellent managers of their diseases unless psychopathology is present and medical care is unavailable or is of poor quality. Managing a chronic condition requires active self-management and interventions that assist patients in acquiring the skills and strategies necessary to live with their illness. (34)

Managing a chronic condition requires active self-management and interventions that assist patients in acquiring the skills and strategies necessary to live with their illness. The success rate of disease management in each individual is largely impacted by factors such as their social and physical environments, the age of the patients, the type of disease and a range of other factors that can influence disease management, such as family involvement which is the most influential factor after the patient. Other factors include clinician expertise, environmental support, community awareness and support. (35)

Patients with chronic conditions make daily decisions about their illnesses. This is the reason why self-management plays a crucial role in chronic conditions. This creates a new paradigm for chronic diseases: the patient-professional partnership involving collaborative care and self-management education. Self-management education can help patients to have the best possible quality of life while having a chronic condition, by teaching them problem-solving skills. In contrast, traditional patient education offers only technical skills and information. Self-efficacy is a central concept in self-management, which is the confidence that an individual has to carry out a necessary behaviour to achieve a desired goal. Self-efficacy is enhanced when patients successfully solve patient-identified problems. (36) Self-management plays an important role in a condition such as achalasia, where treatment options are primarily to alleviate symptoms and are invasive for most people. Regardless of the type of treatment, patients must self-manage their condition and symptoms. The implementation of behaviour change interventions plays a vital role in promoting healthier lifestyles and empowering people living with achalasia to take control of their health, thereby further enhancing the effective management and self-management of their chronic condition. In the following section, the management of chronic conditions using behaviour change interventions is discussed.

1.8 Managing chronic conditions through behaviour change interventions

Chronic conditions such as heart disease, stroke, respiratory and diabetes are the leading cause of death worldwide. These chronic conditions account for 60% of deaths in the world. (37) People with chronic illnesses can adopt a healthier lifestyle through measures such as smoking cessation, increased physical activity and improving diet to extend longevity, reduce the recurrence of an event and improve their quality of life. (37) However, it is difficult to change established behaviour that has developed in response to a long-term health condition and its associated problems. This is demonstrated by the difficulties in addressing long-term societal concerns such as smoking, obesity, and excessive alcohol consumption, even when the health benefits of a ‘healthy’ lifestyle seem persuasive. (38) Thus, recognising the importance of behaviour change becomes crucial in effectively managing chronic conditions.

The concept of behaviour change encompasses the adoption of healthy and novel lifestyle behaviours that are more suitable to the individual’s requirements. (39) The effective implementation of behavioural change necessitates the proficient utilisation of various disease-related skills. Incorporating skill training is necessary to effectively target and address specific skill deficiencies. (39) Within the context of self-management interventions, behaviour change is often attributed to the enhancement of self-efficacy, as proposed by Bandura in 1977. (40 These interventions commonly employ self-management techniques that emphasise the modelling of persuasive communication by healthcare professionals and the reinterpretation of physiological symptoms, as discussed by Barlow et al. in 2000. (41) Notably, these technologies tend to advocate for standardised approaches in addressing the needs of patients and clients. (42)

Healthcare providers can use behavioural techniques to help people with chronic illnesses take better care of themselves. Techniques such as goal setting, making sure the patient is ready for self-care, breaking self-care tasks into small, achievable steps, getting personalised feedback, self-monitoring, establishing social support networks, and making sure the patient is committed to key tasks are invaluable tools in facilitating behaviour change. These methods can be used alone or in combination to support individuals in committing to key tasks and achieving sustainable behaviour change. (43)

Richardson, Wingo, Zack, Zahran & King (2008) conducted a study on the Health-Related Quality of Life (HRQoL) of breast cancer survivors aged 20-64. They discovered that those who felt their lives were majorly impacted by cancer and engaged in unhealthy behaviours experienced a lower HRQoL. (44) In a systematic review of literature, Llewellyn, McGurk & Weinman (2005) centred their analysis on psychosocial and behavioural factors. They deduced that poor social support, dissatisfaction with information, depressive symptoms, and behavioural issues (such as alcohol and smoking abuse) are correlated with a diminished HRQoL. (45) These findings underline the importance of change in the management of chronic illnesses. Given the considerable influence these behaviours can have on mortality rates, the likelihood of further adverse events, and the overall quality of life, prioritising behavioural change is crucial. By addressing the challenges associated with changing established behaviours and leveraging evidence-based techniques, healthcare providers can empower individuals to adopt healthier lifestyles, leading to better self-management and improved health outcomes in the context of chronic conditions. The successful implementation of behavioural change interventions for the management of achalasia is dependent upon an in-depth understanding of the principles of self-efficacy and associated theories. These concepts offer significant insights into individuals' beliefs, motivations, and capacity to embrace and sustain health-promoting behaviours.

1.9 Self-efficacy and related theories

People living with long-term conditions, such as stroke, must make modifications, such as learning new behaviours and/or changing their lifestyle. However, it is not easy to make these changes. Self-management has always existed, whether through self-help organisations, family support, or community support. (46) Regardless of the need for society and healthcare to create appropriate institutions for independent living, the question of individualistic and psychological characteristics mediating successful self-management persists. People who believe their abilities to be effective post-stroke may engage in self-care activities that not only modify and improve on achievements gained during rehabilitation but also aid in maintaining progress and function. Knowing individualistic aspects such as the level of confidence and emotional responses of individuals working towards certain goals post-stroke may also assist health practitioners in appreciating the various responses to rehabilitation. (47) One psychological construct that has received a lot of attention in the management of numerous chronic diseases is self-efficacy. Bandura (1977) introduced self-efficacy as a foundation of his Social Learning Theory. It is described as "people's beliefs about their capabilities to produce designated levels of performance that exercise influence over events that affect their lives". (40) Self-efficacy beliefs can influence how people feel, think, motivate themselves, and act in relation to their health. (47) The theory of self-efficacy proposes that the direction, intensity and persistence of behaviour depend on the individual's ability to carry out a behaviour. (48) An individual's source of self-efficacy is the information and feedback they receive while carrying out a task. Self-efficacy comes from four main sources: mastery experiences, vicarious experiences, verbal persuasion, and physiological feedback. (47)

1.9.1 Mastery experiences

According to Bandura, the most influential factor in shaping an individual's self-efficacy is their past successes, also referred to as 'performance achievements'. This involves learning through personal experiences of mastery, where successfully completing tasks or reaching goals helps to boost self-efficacy. As individuals become more proficient in a given task, their belief in their own abilities to successfully complete that task is reinforced, thus enhancing their overall sense of self-efficacy. (49)

1.9.2 Vicarious experiences

The second source of self-efficacy is vicarious experience, which is learning via the observation of others or events. A person's sense of mastery can be enhanced by watching others (models) who are viewed as being similar to them succeed at a task. This can have an impact on how they feel about their own self-efficacy. This is especially true if the work or activity has previously been thought of as challenging. Similarly, by watching the failure of models, the observer's perceived self-efficacy could decrease. (49)

1.9.3 Verbal persuasion

Verbal persuasion, or the use of encouraging and affirming language by a respected individual, can increase a person's confidence in their own abilities. This positive reinforcement can come from a healthcare professional, a family member, or any key figure in the person's life. However, it's crucial that verbal persuasion is tailored such that the individual perceives their performance of a certain skill as successful. In other words, the messages of affirmation should align with the individual's experiences and enhance their sense of achievement. (50)

1.9.4 Physiological feedback

Physiological feedback is the process through which an individual's efficacy beliefs are shaped by the input produced by his or her own physiological state. Individuals can boost their self-efficacy by interpreting their physical and emotional emotions as positive rather than negative, e.g. walking unassisted after a stroke without feeling unstable. (50)

1.10 Use of theories in behaviour and behavioural changes

Generally, interventions to alter health-related behaviours have moderate impacts and may be more effective if based on relevant theory. (51) The majority of theories applied to public health interventions tend to emphasise on individuals' capability and motivation, whereas context and social elements are rarely mentioned. By incorporating social, cultural and economic factors that can influence behaviours, the effectiveness of interventions can be increased. (50) In order to potentially increase the effectiveness of interventions, it is crucial to understand behaviour and behaviour change. The behaviour change approach promotes health through individualised, context-appropriate adjustments in lifestyle. The most efficient and successful method for reducing sickness must be persuading people directly to change their behaviour, given that certain behaviours cause illness. This argument is appealing to decision-makers because it promises demonstrable benefits in a short period of time, may address health problems with a high prevalence, is relatively straightforward, and delivers savings on health care services, particularly for those with chronic diseases. (52)

Theory is the collection of what we know about how things work (mediators) and how things change (moderators), as well as our assumptions about what human behaviour is and what affects it. (51) The use of theory is seen as an important part of designing and evaluating interventions and putting together a body of evidence. (51) Currently, theories used in public health and behaviour change interventions tend to focus on individual and sometimes interpersonal factors rather than social and environmental factors on a larger scale. (53) Capabilities and motivation are often looked at, but context, which includes social and environmental factors, is looked at less frequently. (51) A study carried out by Davis et al. identified eighty-two theories of behaviour and behaviour change. They accomplished this by consulting a multidisciplinary project advisory group, examining electronic databases, conducting web searches, following forward and backward reference lists, and manually reviewing key behavioural science journals. (51) Out of the 82 theories, the Transtheoretical Model of Change (TTM) illustrates how individuals progress through five stages when changing behaviour; the Theory of Planned Behaviour (TPB) indicates that intention, influenced by attitudes, subjective norms, and perceived control, predicts behaviour; the Social Cognitive Theory (SCT) which underscores the significance of self-efficacy and the social context in learning and behaviour change and the Information-Motivation-Behavioural-Skills Model (IMB) proposing that the interaction of information, motivation, and behavioural skills primarily determines health behaviour were most frequently applied in the literature. Various theories have the potential to be applicable to interventions at different levels. For instance, theories of individual behaviour are more relevant to interventions directed at individuals and teams, whereas theories of organisational change have the potential to be more applicable to interventions directed at hospitals or NHS trusts. (54)

Behaviour and behaviour change are complex phenomena that demand a robust, theory-driven approach to effectively modify them, especially in the context of chronic conditions like achalasia. The Behaviour Change Wheel (BCW) framework, a systematic and comprehensive model for understanding behaviour and designing behaviour change interventions, is one such theory that can be employed. The BCW offers a methodical approach to developing interventions that effectively tackle the multifaceted issues associated with changing behaviour in achalasia. It takes into account the multitude of factors that can influence a person's behaviour, making it a suitable choice for creating tailored, effective interventions. In the following section, we delve deeper into how to design an intervention using the Behaviour Change Wheel.

1.11 Intervention design using the Behavioural Change Wheel

Creating, implementing, and assessing interventions to alter established behaviour patterns can be difficult. Frequently, interventions are created without a systematic procedure and without utilising the facts and theories provided by the behavioural and social sciences. Research suggests that the most effective interventions for changing behaviour are those that target the population, community, and individual levels at the same time. (55) There are many frameworks to enable a systematic approach to intervention development. In 2010, a systematic evaluation of behaviour change identified 19 frameworks and rated them in terms of comprehensiveness, coherence, and linkages to a behavioural model. (56) Because no framework matched all three criteria and there was some overlap among the frameworks, they were merged into a single framework with two levels, one representing intervention functions and the other representing higher-order policy categories. The result was the Behaviour Change Wheel (BCW), which gives a systematic way to describe interventions so that their results can be linked to mechanisms of action. This can help to determine why an intervention may not have had the desired effect. At the centre of the wheel is the Capability-Opportunity-Motivation-Behaviour (COM-B) model, which links the nine intervention functions and seven policy categories. The Behaviour Change Wheel (BCW) is comprised of three distinct layers, each providing a different level of insight into the behaviour and its modifiers, as depicted in Figure 5. The hub of the wheel identifies the sources of the behaviour that could be useful targets for intervention. The COM-B model in Figure 6 provides a simple framework for understanding behaviour by conceptualising 'capability' (physical and psychological), 'opportunity' (physical and social), and motivation (automatic and reflective) as three essential factors for behaviour. Around the COM-B model is a layer of nine intervention functions to choose from, each of which can be used to address deficits in one or more of capability, opportunity, or motivation. The outer layer, the rim of the wheel, defines seven forms of policy that can be used to deliver intervention functions.

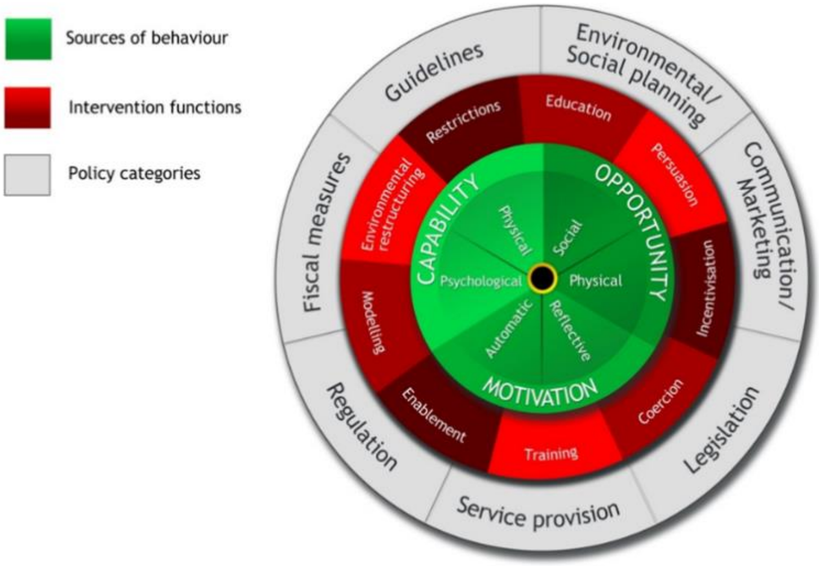

Figure 5. The Behaviour Change Wheel developed by Michie et al. [(56)]

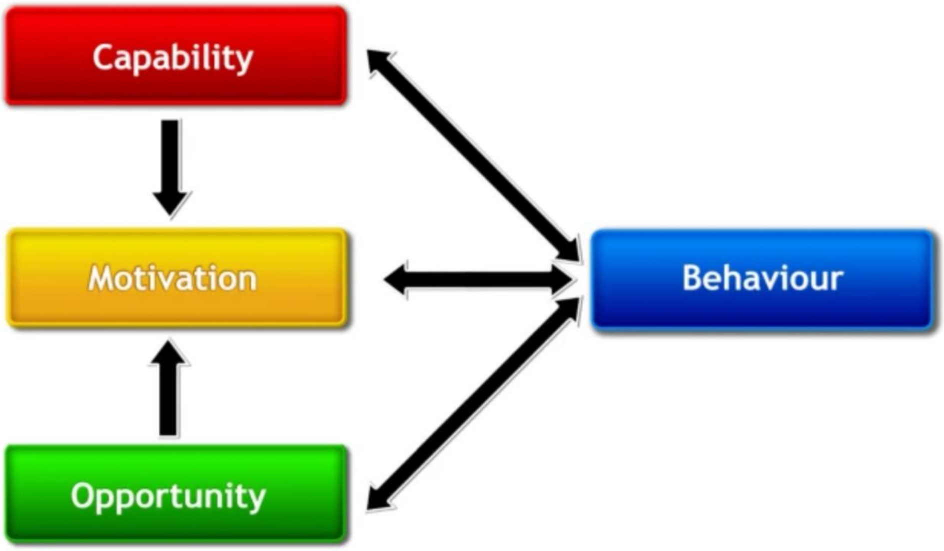

Figure 6. The COM-B model

There are a few stages in order to design an intervention using the BCW and the COM-B model. In stage 1, it is important to define the problem in behavioural terms and select a target behaviour. The intervention designers will need to create a long list of all potential behaviours that might be relevant to the problem to be addressed. Once a target behaviour is selected, it needs to be specified in detail, such as a detailed description of the behaviour, who need to perform the behaviour, what the person needs to do differently to achieve the desired behaviours, when they have to do it, where will they do it, how often they have to do it and with whom they will do it. It is also important to identify what needs to be changed.

Stage 2 involves utilising the Behaviour Change Wheel (BCW) to systematically identify potential intervention functions. The BCW provides a comprehensive framework that encompasses a broad range of interventions, offering a systematic approach to selection based on the specific needs and context of the behaviour change. The nine intervention functions include education, persuasion, incentivisation, coercion, training, restrictions, environmental restructuring, modelling and enablement.

Before implementation, designers can use the APEASE criteria to determine which intervention functions, policy categories, behaviour change techniques, and modes of delivery best fit their context. These considerations help identify strategies most likely to be effectively utilised and impactful. The term APEASE consists of Affordability, Practicality, Effectiveness and cost-effectiveness, Acceptability, Side-effects/safety, and Equity. After identifying intervention functions the policy categories need to be identified, which are decisions made by authorities that support the delivery of intervention functions. The final and third stage of intervention design is identifying behaviour change techniques and identifying the mode of delivery. Behaviour change techniques are an active component of an intervention designed to alter behaviour. This is achieved using the Behaviour Change Techniques Taxonomies, which consist of 9 distinctive, non-overlapping behaviour change techniques.

1.12 Study rationale

The rationale for this study stems from the understanding that achalasia, a rare and chronic condition, has not received significant attention in the literature. People living with achalasia face various challenges, including difficulty swallowing, chest pain, and regurgitation of food, which can significantly impact their daily lives. These challenges can also prevent patients from participating in social activities that involve food, which can lead to social isolation and a decreased quality of life.

Despite the impact of achalasia on patients' lives, the non-medical aspects of this condition, such as self-management strategies and research initiatives to raise awareness, have not received adequate attention in the existing literature. Consequently, there exists a considerable knowledge gap regarding the experiences of people living with achalasia, encompassing various aspects such as the psychosocial challenges they encounter and the profound influence of the condition on their daily lives. Addressing this knowledge gap is of paramount importance to develop comprehensive interventions that can effectively improve the quality of life for people living with achalasia. Therefore, it is essential to expand research efforts beyond the medical aspects and encompass the non-medical dimensions of achalasia, including self-management approaches and initiatives aimed at increasing awareness and understanding of this condition. Furthermore, while medical interventions play a crucial role in managing achalasia symptoms, there is a pressing need to understand the holistic impact of the condition on individuals' well-being, including its psychosocial ramifications. By exploring the lived experiences of achalasia patients, this thesis aims to provide a more comprehensive understanding of the condition and contribute to the development of patient-centred care approaches that address both medical and non-medical aspects of the disease.

1.13 Aims and objectives

The aim of this thesis is to thoroughly examine the lived experiences of people living with achalasia, encompassing their everyday life, experience of treatments, and management of the condition, from pre-diagnosis to post-diagnosis stages. This study aims to contribute to the understanding of achalasia and its management, ultimately improving the lives of those affected by this condition.

1. Specific research objectives are: To map out the healthcare experiences and steps involved in the transition from pre-diagnosis to post-diagnosis for people living with achalasia, capturing the entirety of their journey with this condition. This objective seeks to provide a comprehensive understanding of the challenges, emotions, and adaptations encountered by people living with achalasia during their entire journey with achalasia.
2. To co-design an intervention using the COM-B model with the aim of identifying a key behaviour related to challenges faced by people living with achalasia. The goal of this objective is to subsequently develop practical tools and strategies to address these identified behavioural challenges.
3. To assess the feasibility of the co-designed intervention. This objective involves evaluating the practicality, acceptability, and potential effectiveness of the intervention through testing and gathering feedback from participants. The findings will inform the future development and implementation of the intervention to ensure its relevance and viability for people living with achalasia.

By addressing these objectives, this thesis aims to contribute valuable insights into the experiences of people living with achalasia, while also providing an evidence-based intervention that can improve their quality of life and self-management strategies. The significance of the studies presented in this thesis is both theoretical and practical. The theoretical significance arises from the recognition that achalasia, an uncommon and chronic condition, has received little attention in the scientific literature. Therefore, the studies in this thesis aim to fill this gap by exploring the lived experiences of people living with achalasia and providing an in-depth understanding of the challenges they face. The practical significance of the studies in this thesis arises from its focus on achalasia, a chronic condition with a profound impact on peoples' quality of life. This thesis aims to co-design an intervention to enhance the social eating experiences of people living with achalasia, a significant step towards improving their quality of life. By addressing the discomfort often associated with food-related social activities, this intervention has the potential to enhance patients' overall social engagement and well-being.

The findings of this thesis will contribute to the body of knowledge on achalasia and the experiences of people living with this condition. Additionally, the co-designed intervention can provide a practical solution to the challenges faced by people living with achalasia. Finally, the feasibility study will provide valuable insights into the effectiveness of the co-designed intervention. Overall, this thesis will provide an in-depth understanding of the challenges patients face and the impact of the condition on their daily lives and has the potential to significantly improve the quality of life of people living with achalasia.

1.14 Overview of thesis

This thesis examines the lived experiences of people living with achalasia, a chronic health condition, and investigates their self-management strategies throughout their journey from before diagnosis to after treatments. The thesis is divided into six chapters, each contributing to the overall objective of the study.

Chapter 1 is the introduction chapter which provides an overview of achalasia, including its definition, history, prevalence, causes, and pathophysiology. It reviews available medical treatments and emphasises the importance of self-management for people living with achalasia. Chapter 2 is the methodology chapter which describes the research paradigm, providing insights into various theoretical perspectives and research methods and detailing the mixed-methods approach used. It discusses the research design, data collection methods (focus groups, interviews, online surveys), and data analysis techniques (triangulation, constant comparative analysis, content analysis.), along with addressing the ethical considerations.

Chapter 3 is the first study that mapped the experiences of people living with achalasia from diagnosis to long-term management. It describes the methodology, sample population, process mapping sessions, and data analysis. A process map was developed from this study to show the steps involved in people's journey. By developing the process map, gaps and challenges in their journeys were identified, highlighting the need for an intervention to address specific issues. This led to the subsequent study in chapter 4, where the focus was on co-designing an intervention to target one of the identified challenges. Based on the insights gained from the process map, the second study aimed to prioritise and address the specific challenge related to eating behaviour as identified by people living with achalasia. The research team collaborated with participants to co-design a workbook using the COM-B model as a framework. This model allowed for a comprehensive approach to changing behaviour by addressing capability, opportunity, and motivation factors. The workbook incorporated various activities and exercises tailored to the needs and preferences of people living with achalasia, promoting positive changes in eating behaviour in social settings. This study outlines the rationale, research questions, and objectives. It also describes the method employed in this study, specifically the use of online focus groups. To further evaluate the effectiveness of the co-designed intervention, Chapter 5 focused on a feasibility study. This study aimed to test the recruitment process and the impact of the workbook on participants' eating behaviour, emotional well-being, and social support. By collecting pre- and post-intervention data through questionnaires and conducting interviews, the study provided insights into the feasibility and potential effectiveness of the workbook as an intervention for people living with achalasia. The results presented in this study include the impact the workbook had on participants and changes in eating behaviour and feedback on the workbook usability.

Overall, the sequential progression of the studies in chapters 3, 4, and 5 demonstrates a logical connection and a systematic approach in addressing the gaps identified in the experiences of people living with achalasia. The process map developed in chapter 3 informed the subsequent studies, leading to the development and testing of a co-designed intervention to target specific challenges related to eating behaviour. This approach ensures that the research findings are not only grounded in the experiences of people living with achalasia but also directly applicable to improving their quality of life and self-management strategies. The final chapter provides a discussion on the overall implications of the research findings, the strengths and limitations of the work and recommendations for future research.

Chapter 2

2. Methodology

2. 1 Introduction

The methodology chapter of this thesis provides a comprehensive examination of the research paradigms and methodological approaches utilised across the three studies conducted within this research work. Both qualitative and quantitative methodologies, elucidate their unique characteristics and their application in this work. The participatory action research component of this thesis is highlighted, illustrating the collaborative nature of the research process. This chapter also provides a succinct overview of the various studies that form the core of this thesis. It delves into the detailed methods employed for analysing both qualitative and quantitative research, underscoring the robustness and integrity of the research design. In an effort to ensure the trustworthiness and rigour of the qualitative research, engagement with recognised qualitative research methodologies was maintained, along with ethical considerations and quality control, throughout the study. This chapter thus serves as a guide to the methodological heartbeat of this thesis, illuminating the rigorous and reflective journey embarked upon in this research.

Research is an essential tool in healthcare, providing a deeper understanding of the various processes and outcomes that occur within the field. Qualitative and quantitative research offer different approaches to studying healthcare and can provide valuable insights for practitioners, researchers and users. Qualitative research focuses on understanding the “why” and “how” of a situation, while quantitative research focuses on understanding the “what” and “how much” of a situation. Both approaches are important in healthcare, as they can help inform decisions and develop effective and appropriate policies for the population being served. By combining these two approaches, healthcare providers can gain a more holistic understanding of the services they provide and the outcomes they produce. This thesis used Mixed Method Research (MMR) to understand people’s experiences living with achalasia, co-design an intervention and change their eating behaviour in a social setting. MMR combines both qualitative and quantitative research methods to gain a more holistic understanding of a given topic. (57) This type of research is conducted using qualitative and quantitative data, such as surveys and interviews, to gain a wider understanding of the topic, as well as the ability to cross-reference data from different sources to validate results. Additionally, it can help to provide a better understanding of the relationships between different variables or factors. (58)

2.2 Research paradigms

Research paradigms are sets of assumptions, concepts, values, and practices that are shared by different research communities. They provide the foundation for a particular research approach, helping to shape the research process and ensure that results are reliable and valid. They are important because they allow researchers to agree on the same basic principles and approaches, helping to facilitate communication between researchers. They also help to ensure that research results are consistent and can be compared and contrasted with each other. (58)

Scientific research is the systematic search for knowledge. Research paradigms serve as a lens through which scientific research is conceptualised, conducted, and interpreted. (59) These research paradigms are the philosophies of science. (60) They guide how science is conducted by shaping the following core elements: ontology (how reality is seen), epistemology (how the nature of knowledge is thought of), axiology (the role and values of the research process), methodology (how the paradigm defines the processes of conducting science), and rigour (the criteria used to justify the quality of research in the paradigm). (61,62) Due to the development of human thought and the variety of explanations for the causes and effects of the events that exist in the world, there are numerous philosophical paradigms in use today. (63)

2.2.1 Positivism

The philosophical perspective of scientists who work with the observable reality within society and produce generalisations is known as positivism. (64) The positivism paradigm is a philosophical framework that guides research in various disciplines, including social sciences and natural sciences. It emphasises the use of empirical evidence, objectivity, and the scientific method to study and understand the world. Positivism emphasises the significance of what is presented generally, with a stricter focus on taking into account pure data and facts without being impacted by human interpretation or bias. (65)

2.2.2 Transformative

The transformative paradigm is a framework that actively involves people from culturally distinct groups with the goal of promoting greater social justice. (66) Mertens states that the transformative paradigm puts the lives and experiences of marginalised groups, such as women, ethnic/racial minorities, people with disabilities, and people with low incomes, at the centre of its focus. (67) Upon adopting this paradigm, researchers try to establish a connection between the outcomes of their social research and practical applications, as well as to relate their findings to broader issues of social inequality and justice. (68)

2.2.3 Pragmatism

The pragmatic paradigm developed out of a desire to concentrate efforts on using inquiry to resolve real-world, practical issues. (69) It heavily draws upon modern scientific principles, using the experimental method as an example of how to solve problems in the real world. (70) According to pragmatism, one needs experience to give an event meaning. So, rather than depending on unchanging truths, the aim of pragmatic research is to use the human experience as the main source of information and understanding of the world. (71) The pragmatic approach offers a framework for research that prioritises action and seeks to address practical issues that arise within communities. Like many research paradigms, researchers employing this approach aim to use the most suitable methods for answering research questions, reflecting the flexibility and adaptability inherent in pragmatism. (72)

2.2.4 Constructivism

Constructivism is a research paradigm that emphasises the active role of individuals in constructing their own knowledge, understanding, and beliefs. This perspective is based on the belief that knowledge is created through an active process of engagement with the environment. Constructivism suggests that reality is socially constructed and is constantly being renegotiated as individuals interact with their environment. This means that knowledge is not simply passed on from one person to another but rather is constructed through individual and collective experiences. Constructivism also recognises the importance of context in the development of knowledge and understanding. This means the same knowledge can be interpreted differently based on individual experiences, beliefs, and contexts. (58)

2.2.4.1 Personal reflection on the research paradigm

I have used a constructivist paradigm as a framework for all the studies in this thesis. Constructivism focuses on how people actively create knowledge and meaning based on their unique experiences and interactions with their surroundings. This paradigm has shaped my research approach and methodology, allowing me to gain a nuanced understanding of the lived experiences of people living with achalasia. The notion that knowledge is socially and personally constructed rather than objective or universal is at the heart of the constructivist viewpoint. Accordingly, I have approached my research by recognising the unique perspectives and diverse experiences of people living with achalasia. Rather than seeking absolute truths or generalisable findings, I have focused on exploring the individual stories, meanings, and interpretations of participants. I employed qualitative research methods, including in-depth interviews and focus groups, to embrace the constructivist paradigm. These methods enable me to interact directly with people, allowing me to explore their individual perspectives and the social contexts in which they manage their conditions. The constructivist paradigm has also guided my data analysis. I took an interpretative approach, which involves immersing myself in the data, identifying patterns and themes, and interpreting their meanings in collaboration with the participants. This iterative process allows me to co-construct knowledge and meaning through dialogue and engagement with the participants, ensuring that their voices and perspectives are central to the research findings. Additionally, the co-design of the intervention in my study was influenced by the constructivist paradigm. Recognising that knowledge is not solely produced by the researcher but is co-constructed through collaboration, I have actively involved people in the development of the intervention. Their knowledge, experiences, expertise, and insights have shaped the design process, ensuring that the intervention meets their unique requirements and aligns with their everyday realities.

The constructivist paradigm has also guided my reflexivity as a researcher. I acknowledge that my own experiences, biases, and perspectives shape the research process and interpretations. To elaborate further, my experiences refer to the various encounters and interactions I have had throughout my life, including both personal and professional experiences. These experiences contribute to the lens through which I perceive and understand the world, influencing my research questions, methodologies, and analytical frameworks. Biases, on the other hand, are the predispositions and preconceived notions that I may hold, consciously or unconsciously, which can impact the way I approach my research. These biases may arise from my cultural background, educational upbringing, or personal beliefs, among other factors. Finally, my perspectives encompass the unique viewpoints I bring to the table as a researcher. These perspectives are shaped by my academic training, disciplinary background, and intellectual influences. For a more in-depth exploration of how these factors influence my approach to this research, please refer to Section 6.4 on personal reflexivity.

Through ongoing self-reflection and engagement with the participants, I have sought to remain aware of my influence and actively engage in critical dialogue to challenge and refine my own assumptions and interpretations. In the initial stages of my research, I held a particular assumption that participants from a certain demographic would have similar experiences and perspectives on the topic. However, during the data collection phase, I encountered diverse and contrasting viewpoints among the participants within that demographic. To challenge my assumption, I actively engaged in reflective discussions with the participants, asking probing questions and seeking clarification on their individual experiences. This process allowed me to recognise the limitations of my initial assumption and develop a more nuanced understanding of the topic. During the analysis of qualitative data, I noticed a recurring theme that aligned with my preconceived ideas. However, I actively sought disconfirming evidence and alternative explanations to challenge my initial interpretation. I engaged in critical dialogue with fellow researchers, presenting my findings and inviting their perspectives. Through these discussions, I was able to recognise the influence of my own biases and consider alternative interpretations that enriched the analysis. While conducting interviews, I encountered participants who shared perspectives that were contrary to my own beliefs and values. Instead of dismissing or disregarding their viewpoints, I actively engaged in empathetic listening and asked probing questions to better understand their reasoning and experiences. This allowed me to challenge my own assumptions and broaden my perspective on the topic.

By adopting a constructivist paradigm in my studies on people living with achalasia, I have been able to embrace subjectivity, complexity, and contextuality. The concept of subjectivity is highlighted in the unique interpretations and experiences of each individual in their experience with achalasia, an aspect that was extensively considered when analysing the data. The complexity is evident in the multifaceted interplay between the people's psychological state, their physical health, and their social environment, all of which influence their experience of the disease and the effectiveness of treatments and self-management strategies. Finally, the contextuality of the research was underscored by how the individual's socio-cultural environment and personal history shaped their perceptions and management of the disease. This approach has allowed me to explore deeply into the rich and diverse experiences of people living with achalasia, recognising the multifaceted nature of their condition and the social influences that shape their journey. Ultimately, the constructivist paradigm has enhanced the depth and richness of my research, enabling a more comprehensive understanding of achalasia from the perspectives of those directly affected by it.

2.3 Qualitative and quantitative and mixed-method research

Quantitative and qualitative approaches originate from distinct philosophical traditions within the realm of scientific inquiry. The primary distinction between these approaches resides in their perspectives on ontology and epistemology. (73) The quantitative approach is rooted in positivism, which adopts a realist stance and asserts the existence of an independently existing reality that can be objectively described. This paradigm holds an ontological position that objective reality exists regardless of human perception. Furthermore, it posits the existence of an ultimate truth, suggesting that there is only one truth. (74)

The qualitative tradition draws its foundation from interpretivism and constructivism, both of which are rooted in an idealist perspective. (74) Idealism, as an ontological view, posits that reality is contingent upon an individual's mental structures and activities. (75) This standpoint highlights that there is no singular reality but rather multiple realities that are constructed or interpreted by individuals. (76) Due to the social and psychological constructs, reality is perceived as an intersubjective creation influenced by the collective interpretation and construction of individuals. Qualitative methods encompass a variety of techniques for data collection and analysis. These methods commonly involve purposive sampling, which entails selecting participants based on specific criteria that align with the research objectives. Additionally, qualitative researchers frequently employ semi-structured, open-ended interviews as a means of gathering data. This method was used in all three studies of this thesis. These interviews allow for flexible and exploratory conversations, enabling participants to provide rich and detailed insights into their experiences, perspectives, and interpretations. The qualitative approach values the depth and context provided by such methods in understanding the complexities of human behaviour and social phenomena. (77) Both types of research can be used together to provide a more comprehensive picture of the research topic.

Mixed method research involves a researcher utilising both qualitative and quantitative research approaches in different stages of a research project. The aim of this is to gain a more comprehensive understanding of the research problem at hand. (78) In mixed-method research which was used in the final study of this thesis, quantitative and qualitative methods work in harmony. The findings from one method are leveraged to expand upon or provide further context to the results from the other method. In the realm of mixed methods research, the concept of integration - the interplay or exchange between the qualitative and quantitative components of an investigation - holds significant importance. (79) There are three strategies that could assist health researchers in merging data or outcomes in their mixed methods research, illustrating how these can augment the insights derived from such an approach. (80) These strategies help to address the multifaceted nature of research questions in health studies, offering a more nuanced and comprehensive understanding of the phenomena under investigation. They add depth and breadth to the exploration, providing richer data for analysis.

Researchers frequently employ both qualitative and quantitative methodologies to explore different facets of a single research question, often using a process known as triangulation to combine and validate these findings. Triangulation in this context refers to using various methods to study an issue to achieve a more holistic understanding. Techniques for triangulation occur at the interpretation stage and include identifying where findings from different methods converge, complement, or contradict each other. (81) Notably, discrepancies between findings are not seen as errors but as opportunities for deeper understanding. A specific method, known as the triangulation protocol, involves creating a "convergence coding matrix" to visualise and assess the agreement, partial agreement, or dissonance among different study components. Ultimately, this process helps researchers identify overarching "meta-themes" that cut across the findings from different methods, providing a more comprehensive analysis. (80)

Moran-Ellis and colleagues propose an alternative method for integrating qualitative and quantitative findings in a study, known as "following a thread." This technique commences at the analysis phase of the research. It begins with an initial assessment of each component to pinpoint crucial themes and inquiries for additional exploration. Then, a specific question or theme, referred to as the 'thread,' is chosen from one component and tracked across other components. Although specific steps are not provided, a visual model is presented for managing between datasets. (82)

Finally, some mixed methods studies are unique in that they provide both qualitative and quantitative data for the same cases. This allows for integration at the analysis stage, wherein all data for a particular case (which could be individuals, groups, organisations, or geographical areas) can be studied together. (83) This might involve comparing people's responses to a survey with their interview transcript, for instance. Alternatively, data for each case can be summarised and displayed in a "mixed methods matrix", with rows representing individual cases and columns showing different collected data. This setup helps researchers to detect surprises or contradictions in the data for a single case and look for patterns across all cases. (80)

2.4 Participatory action research

Participatory action research (PAR) is an approach to research that is focused on the collaboration of researchers and members of the community in order to create meaningful change. It is a process that involves community members and researchers working together to identify common problems, analyse their causes, and develop solutions. PAR is important because it puts the power of research into the hands of the community. This approach allows for a more inclusive and representative form of research, as community members are seen as experts and are involved in the research process from start to finish. Additionally, it allows for solutions to be developed that are tailored to the specific needs of the community. This includes gathering data through surveys, interviews, and field observations and then analysing the data to identify problems and create solutions. Following this, the solutions are implemented through collaborative and participatory action, and the results of this action are evaluated to see if they were successful. (84)

Participatory action research was used as a fundamental methodology for the three studies in this thesis on people living with achalasia. PAR aligns with my belief in empowering individuals and engaging them as active agents in the research process. Through the implementation of PAR, the aim was not only generate knowledge about achalasia but also to actively involve the participants in co-designing and implementing interventions that address their specific needs and concerns. Close collaboration with people living with achalasia and both academic and clinical supervisors established a research partnership based on trust and shared decision-making. From this partnership, the key research questions and priorities were identified, ensuring that the research process was relevant and meaningful to the participants. This collaborative approach fostered a sense of ownership and empowerment among the participants, recognising them as experts in their own experiences with achalasia. Throughout the research journey, regular meetings were facilitated with participants, where they actively contributed their insights, experiences and expertise through focus groups and workshops. Subsequently, meetings with academic and clinical supervisors were held to discuss the findings.

Knowledge and understanding of the challenges faced by people living with achalasia were co-created through conversation and shared reflection.

This participatory approach extended to the co-design of interventions aimed at addressing the most pressing issues, such as eating in a social setting. The involvement of the participants did not end with the design phase; it continued through intervention implementation and evaluation. They contributed feedback and suggestions for improvement while actively taking part in the intervention activities. Based on the participants' real-world experiences and ongoing engagement, this iterative process enabled continuous learning, adaptation, and intervention improvement. The use of PAR helped create an environment that was welcoming and safe for open discussion and where everyone felt heard, valued, and empowered. It enabled the bridging of the gap between academia and practice, ensuring that the research findings and interventions directly addressed the needs and aspirations of those affected by achalasia. By employing participatory action research in this thesis, the intention was to go beyond the traditional researcher-participant relationship, actively involving the participants as co-researchers and agents of change. Through this collaborative approach grounded in the constructivist paradigm, the aim was not only to contribute to the academic knowledge on achalasia but also to effect meaningful improvements in the lives of people living with this condition. This approach acknowledges the subjective and co-constructed nature of knowledge, enabling a more nuanced understanding of the lived experiences of people living with achalasia.

2.5 Overview of studies in the thesis

This thesis is underpinned by a constructivist research paradigm, which enables a robust and meaningful exploration of the research questions. Through the integration of diverse methodological approaches within the constructivist paradigm, each study in this thesis offers a unique perspective that, in combination, builds a nuanced and holistic understanding of the topic at hand. The first study presented in chapter 3 of this thesis aimed at gaining an in-depth understanding of the experiences of people living with achalasia, which served as the foundation for subsequent investigations. Through the use of process mapping, the experiences of people living with achalasia were carefully examined and comprehended, from diagnosis to long-term management. The primary objective of the first study was to employ a process map methodology to map the steps involved in people's journey. This study aimed to identify potential areas that necessitate further input or attention. The data obtained from this study were synthesised and visually presented through the use of a process map. Following the findings from the process map study, the second study, presented in chapter 4, focused on co-designing an intervention for people living with achalasia. The primary research question for this study was: 'What specific eating behaviours do people living with achalasia desire to modify, and how can an intervention be co-designed to target these prioritised behaviours?' This investigation began with identifying and prioritising specific eating behaviours from the target population's perspective, leading to the development of a tailored intervention addressing these identified needs. This intervention co-design study involved the participation of people living with achalasia in online focus groups, wherein a model of behaviour change was used to structure the collection of qualitative data and subsequently utilised to create a workbook. For the third study, a mixed-method approach was adopted, combining qualitative and quantitative methodologies. The primary objectives of this study were three-fold: to assess the feasibility of recruitment and to evaluate the practicality and usability of the co-designed intervention. Additionally, this feasibility study explored measures that could potentially be used to assess the effectiveness of this intervention in changing individuals' eating behaviours in future research. The aim of the quantitative aspect of the research was to analyse and explore the relationships, patterns, and trends within the collected data in order to provide an insight into the research topic. The utilisation of descriptive statistics played a key role in achieving this aim by summarising and presenting the data in a clear and concise manner. Data for this quantitative analysis were collected through online pre- and post-intervention questionnaires. Simultaneously, the qualitative aspect of the research sought to delve deeper into the subjective experiences of the participants. The one-to-one online interviews enabled us to capture detailed personal insights, enriching the quantitative findings with nuanced understandings of the participants' lived experiences. This integration of quantitative and qualitative methodologies provided a holistic view of the research topic, enhancing the robustness of our findings and conclusions.

2.6 Methodological approaches

During the process of developing each of the studies, a variety of research approaches were taken into consideration. The appropriateness and applicability of the approach in terms of addressing the research questions had a role in the decision-making process. The research was conducted in three distinct phases. The first phase involved a process mapping study and the second phase focused on co-designing an intervention. Finally, the third phase assessed the feasibility of the intervention through both quantitative and qualitative methods.

2.6.1 Qualitative research

2.6.1.1 Process map

The first study involved the development of a process map to effectively illustrate and map the experiences of people living with achalasia from before diagnosis to after treatment and long-term management of achalasia. Process mapping lets us "see" and understand the patient's experience by breaking the management of a specific condition or treatment into a number of events or steps (such as activities, interventions, or staff interactions). The order of these steps can be seen as a patient pathway or process of care. (85) The information yielded through process mapping has the potential to facilitate the restructuring of the patient pathway, thereby enhancing the quality and efficiency of clinical management. Additionally, it can enable a shift in the emphasis of care towards the activities that are most highly prioritised by the patient. (86) Additionally, studies have shown that a process map is especially helpful for mapping out complicated healthcare procedures, as it provides teams involved in Quality Improvement Projects (QIPs) with knowledge of the actual workflow “work as is” rather than an idealised or theoretical version “work as imagined”. (87)

Increasing process transparency is one potential benefit of creating and using process maps. In a transparent process, all essential elements and stages are consistently visible and understandable for everyone. (88) Process mapping needs a planned method because even seemingly simple patient journeys can be complicated and have many steps that depend on each other. (85) People taking part in the process mapping should have fun and be creative during the process. Similar to auditing, it should not be confrontational or critical, and it should not be used to “name, shame, and blame.” (89) Upon development of a process map, an in-depth representation of a process and its various components can be observed and analysed. (90) Hence, the development of a process map is a two-fold process. Initially, the map is created to provide an in-depth representation of the process and its various components. Once developed, the map acts as a comprehensive tool for observation and further analysis. Hence, it’s both an initial development phase and a subsequent analysis phase that together constitute the comprehensive process mapping approach. Through the process mapping technique, researchers can learn more about the process and collect data about how long each step takes, how long people have to wait, how the process flows, and/or how people move through the process space. When a process is known, the maps can be used to find the steps where reliable metrics can be collected to measure how well that step works or what happens when the process is finished. Also, chances to cut down on mistakes and waste can be found and measured. (90)

The primary aim of the first study was to map the journey of people living with achalasia, from initial symptoms to the long-term management of their condition, while also highlighting areas where further support is required. The study employed semi-structured mapping sessions to explore and understand the care pathways for individuals who have been diagnosed with achalasia. An in-depth representation of the people’s s journey through their achalasia treatment was gained. This map illuminated the various components of the process and facilitated a detailed analysis of the sequence of steps. Using this developed map as a tool, it was possible to delve into the details of the process, gather data about the rough duration of each step, understand the flow, and ascertain how patients navigated the healthcare system. Through a thorough understanding of this process, specific steps were identified where reliable metrics could be gathered to evaluate the efficiency of that stage, as well as the outcome upon completion. The process map also sheds light on potential areas where inefficiencies could be identified, and improvements could be made. The University of Reading’s Research and Ethics

Committee granted a favourable ethical opinion for this study (Study One: UREC-13/38) prior to initiating data collection.

2.6.1.2 Online focus groups

In the second study, online focus groups were utilised to co-design an intervention aimed at assisting people living with achalasia in modifying one of their most challenging eating behaviours. In recent years, there has been a significant surge in the utilisation of online qualitative data collection. This has provided researchers with the opportunity to conduct research in a more efficient and useful manner. (91) Online focus groups offer participants the flexibility to contribute at their convenience and from any location while also offering the option to remain anonymous (if they wish to keep their cameras off), thereby reducing the potential for fear or self-censorship. (92) In addition to accommodating participant preferences, the significance of conducting data collection online is amplified in an unpredictable future where the possibility of pandemics may restrict in-person research for the sake of health and safety. (93) A focus group is a method that entails conducting detailed group interviews with participants who are chosen based on a purposive sampling of a particular population. Although not necessarily representative, this group is selected to focus on a specific topic. (94) The selection of participants for this type of research is based on specific criteria, including their ability to contribute relevant insights on the topic, falling within a designated age range, possessing similar socio-demographic characteristics, and exhibiting a willingness to engage in open dialogue with both the interviewer and other participants. (95) The group dynamics associated with focus-group interviews are a notable characteristic, resulting in a broader and more profound range of data generated through the social interaction of the group in comparison to data obtained from one-on-one interviews. (94) Through the exchange of narratives, the sharing of personal experiences, and the provision of diverse perspectives, participants in focus groups contribute to the discussion by revealing their preferences and aversions, desires and requirements, and opinions and recommendations. In comparison to individual interviews, the dynamics within focus groups often contribute to a richer and more emotive discussion, with a wider range of perspectives and insights being shared among participants. (91) The focus group for the second study was carried out via Microsoft Teams, which is an online platform. The University of Reading's Research and Ethics Committee gave a favourable opinion for this study (Study Two: SREC 40/2020) prior to data collection. study.

2.6.1.3 Semi-structured interview

The third study employed a combination of qualitative and quantitative data. It consisted of online one-to-one interviews with those who had completed the intervention and volunteered to give their feedback. In qualitative research, interviews are frequently employed as the primary method of data collection (96) and the semi-structured format is the most common interview technique in qualitative research and healthcare settings. (97) The semi-structured interview approach has been noted for its efficacy in encouraging mutual exchange between the interviewer and interviewee, facilitating the interviewer's ability to spontaneously generate additional inquiries in response to the interviewee's answers, and affording opportunities for the interviewee's unique verbal expressions. (98) The semi-structured interviews are widely recognised for their ability to facilitate deep conversation, adaptability, and generative nature, which promotes new ideas. Furthermore, the perspectives are expressed in their natural forms, which include non-verbal messages. (99) Semi-structured interviews are also the preferred approach for data collection in cases where the researcher aims to gain a deeper understanding of the participant's individual viewpoint, as opposed to a generalised understanding of a given phenomenon. (100) In the final study, this approach was used to gain feedback on the usability and practicability of the workbook from the participants on the co-designed intervention. A favourable ethical opinion was granted through the University of Reading School of Chemistry, Food and Pharmacy Research Ethics Committee (SREC 51/2022).

2.6.2 Quantitative research

2.6.2.1 Online questionnaire

Questionnaires are a common way to collect data for academic or marketing research. (101) Online survey methods offer convenience in a number of ways, including the ability for respondents to answer at a time that is suitable for them, spend as much time as necessary to reply to questions and finish the survey in numerous sessions. Similar to paper-based surveys, online questionnaire surveys are capable of question variety (e.g., dichotomous questions, multiple-choice questions, scales), skip irrelevant questions for subgroups in the sample (e.g., no pregnancy questions for men), and even gather open-ended questions (qualitative data) through a free text box. (101) A researcher who wants to gather primary data must consider what data should be collected, how many questions should be created, in what order they should be asked, how each question should be worded, and how the questionnaire should be laid out. (101) However, the length of the questionnaire has been a problem for researchers; they should be as brief as possible because a long questionnaire may both lower response rates and make respondents fatigue, contributing to a phenomenon known as responder burden. According to Herzog et al., many researchers believe that survey instruments have a maximum duration beyond which there is a higher likelihood of premature termination, random responding, or other behaviour patterns that lead to results of inferior quality. (102)The aim of the final study was to explore the feasibility of the co-designed intervention in potentially aiding people living with achalasia to enjoy eating in a social setting; therefore, the participants were asked to complete a pre and post-intervention questionnaire. Data were analysed quantitatively by descriptive analysis, which was the most appropriate method of analysis to summarise the extent to which the co-designed workbook was beneficial for people when eating in a social setting. The descriptive analysis allowed for a comprehensive and straightforward presentation of the data, capturing the workbook's effectiveness and variability. This approach was also selected because the sample size was not large enough to support more complex inferential statistics.

2.6.3 Methods for data analysis in qualitative research

In qualitative research, data analysis involves systematically reviewing and organising interview transcripts, focus groups, observation notes, or other non-textual resources acquired by the researcher to deepen their understanding of the phenomena. Coding or categorising the data is a major part of the qualitative data analysis process. It essentially entails making sense of large amounts of data by lowering the volume of raw data, then recognising relevant patterns, pulling meaning from data, and ultimately developing a logical chain of evidence. (103) According to Tesch, there are over 40 approaches to qualitative research. (104) Depending on the study aim, Tesch categorises this range of techniques into three primary orientations. The first orientation, termed the 'language-oriented' approach, is concerned with how language works and how people communicate. The second "descriptive/interpretive" approach is to identify patterns in social phenomena by giving in-depth descriptions of them. The third approach, known as "theory-building," looks for linkages between various social processes. (105) The descriptive and interpretive method of analysis was utilised for the qualitative work that was incorporated into this thesis. This method allowed for a deep delve into the participants' experiences and perceptions, yielding rich, detailed descriptions of their lived experiences. It also facilitated an interpretive analysis that considered the broader context and subjective meanings, enabling the drawing out patterns, themes, and insights that a more structured analytical approach might have overlooked. According to Punch et al., the process of qualitative data analysis comprises three primary components, including "data reduction," "data display," and "drawing and verifying conclusions." (106) There are different approaches to qualitative data analysis. Some examples are triangulation, constant comparative analysis, phenomenological approaches, narrative analysis, discourse analysis and content analysis.

The utilisation of diverse data sources, methods, or perspectives to investigate a research problem or question is commonly known as triangulation in research. The process entails combining various methodologies to improve the trustworthiness, authenticity, and consistency of the results. The utilisation of triangulation in research aids in mitigating the constraints associated with depending on only one method or data source and facilitates a more all-encompassing and strong understanding of the phenomenon being studied. (107) Research triangulation uses four methods, which are data triangulation, methodological triangulation, investigator triangulation and theory triangulation. Data triangulation involves examining the study topic through the use of multiple data sources, enhancing the depth and validity of the research. Interviews, surveys, observations, and documentation are common data collection methods. Researchers can cross-verify and compare the findings using multiple data sources, increasing confidence in the results. Methodological triangulation uses many research approaches to answer the same subject. A researcher evaluating an intervention's efficacy may use quantitative surveys and qualitative interviews to understand the phenomena. Researchers might broaden their perspective and reinforce their results by combining methodologies. Investigator triangulation is using multiple researchers or investigators to do the research. Each researcher's experience, history, and prejudices can assist in uncovering and reducing biases and improving study dependability. Collaborative research teams or independent professionals can gather, analyse, and interpret data. Theory triangulation interprets facts using diverse theoretical frameworks. Researchers can gain a deeper knowledge of the phenomena by exploring multiple explanations. This method helps researchers find patterns, establish links, and explore alternative viewpoints. (105)

Sociologists Barney Glaser and Anselm Strauss created the grounded theory approach for conducting qualitative research. Instead of depending on pre-existing theories or hypotheses, it tries to produce ideas that are "grounded" in the evidence gathered throughout the research process. A conceptual understanding of a social phenomenon may be explored and developed by researchers using grounded theory and empirical data. (108) According to Corbin and Strauss, grounded theory is a comprehensive methodology that facilitates the development of theory based on data that has been systematically collected and analysed. Theoretical frameworks undergo development throughout the research process via the ongoing interplay between data collection and analysis. The constant comparative method is frequently denoted as such due to its utilisation of comparative analysis as a primary feature of its analytical approach. (109)

Constant comparative analysis, originally developed for use in the grounded theory methodology, is a qualitative analytic strategy. It involves comparing pieces of data—such as interviews, statements, or themes—with each other to identify possible relations. The goal is to generate knowledge about common patterns and themes within human experiences by posing analytical questions like: 'why is this different from that?' or 'how are these two related?' The process continues until all data have been compared with each other, contributing to understanding human phenomena within their lived context. This analysis method is commonly used not only in grounded theory studies but also in other methodologies that aim for descriptive or interpretive knowledge, such as naturalistic inquiry, thematic analysis, and interpretive description. (110) According to Krippendorff (2013), content analysis is a research technique that enables the production of reliable and accurate conclusions about the contexts in which texts (or other meaningful materials) are utilised. (111) The fundamental concept underlying content analysis is that of selective reduction. This suggests a process of categorisation wherein the focus of the researchers is on reducing the text to specific categories comprising words or a group of phrases. The identification of particular vocabulary or structures serves as cues for the research inquiry and establishes the scope of the analysis. (112)

Phenomenological approaches to data analysis involve examining and interpreting qualitative data to understand the lived experiences of individuals. The goal is to gain insights into how individuals perceive their experiences and make sense of their world. This type of analysis is often used in social and health sciences, psychology, and education research. At times, researchers may define their methods not by identifying the phenomenological perspective they've taken but rather by referring to the specific theorist whose strategies they are employing in their study. There is a vast array of phenomenological research styles, yet many of the methods most commonly used are rooted in the philosophical teachings of Husserl, focused on ways of understanding (epistemology), and in Heidegger's hermeneutic tradition, which accentuates ways of existence (ontology). These methodologies may vary in how much they permit interpretation, yet both offer ways to deeply delve into data, engage thoughtfully with this data, and produce a rich description that illuminates for the reader the fundamental structures underpinning a specific human experience. (110)

2.6.3.1 Methods for data analysis in this thesis

Content analysis was the method employed when analysing the data for the first study, which was process mapping. As described earlier, content analysis is a type of qualitative data analysis that looks at how the content or qualities of textual data can be carefully analysed and put into groups. It is often used to find patterns, themes, or steps in qualitative data, such as the recordings of focus groups. A systematic approach was followed to develop a process map by employing content analysis of data obtained from focus group sessions. At the outset, the audio-visual documentation of every session of the group discussions was diligently attended to and examined, guaranteeing an in-depth understanding of the information while pinpointing crucial ideas. Subsequently, the unit of analysis was determined in order to proficiently recognise distinct phases within the path of the individuals. Following the identification of units of analysis, suitable codes were assigned that precisely represented the discrete stages or components of the journey. The process of arranging these codes in a methodical manner into cohesive groupings or patterns that include the different stages of the journey was also implemented. The previously mentioned groups or themes were employed to create a process map, which served as a clear and comprehensive illustration of the various stages. Finally, the process map was subjected to a thorough evaluation and analysis conducted by supervisors, aiming to enhance its precision and reliability.

The second study employed a theoretical framework, the COM-B model (see figure 6 in Chapter 1), to guide the co-design process of an intervention. This model offered a comprehensive view of behaviour (Capability, Opportunity, Motivation, and Behaviour), helping shape the intervention's construction and design. However, beyond its formative role in the intervention, the COM-B model also played a critical role in the data analysis. In the data analysis phase, a phenomenological approach was implemented to understand the participants' lived experiences during the co-design process. This comprehensive, phenomenological analysis of the data using the COM-B model was instrumental in guiding the subsequent phase of the study. The data were mapped onto the COM-B model, using its elements as a structural backbone to organise and interpret the experiences shared by the participants. The rich insights gained from this interpretive approach were directly applied to the development of a concrete tool: a workbook designed to facilitate one of the most challenging eating behaviours prioritised by participants. A workbook was structured around the Behaviour Change Techniques (BCTs) as defined by the COM-B model, reflecting the comprehensive understanding of participants' lived experiences gathered from the data. Notably, these BCTs were not solely derived from the study's findings but were also informed by existing literature on effective behaviour change methods. Among the 93 behaviour change techniques (BCTs), common techniques such as goals and planning, feedback and monitoring, social support, and shaping knowledge have been previously found to be effective in changing eating behaviours in other populations, such as in initiatives aimed at behaviour change in individuals with type 2 diabetes and efforts to improve dietary intake among young adults. (113,114) Each section of the workbook was tailored to address a corresponding BCT, providing targeted strategies, exercises, and information based on the insights gained from the data. This meticulous approach ensured that the workbook served as a practical guide for executing the intervention, integrating the BCTs directly into its design and use. It is a tangible outcome of the study's phenomenological analysis, providing a direct link between the research findings and their practical application. The development of this workbook demonstrates the effectiveness of combining the COM-B model with a phenomenological approach in generating rich, applicable insights into influencing human behaviour.

The data and methodological triangulation approach were used in the final study to increase the validity and rigour of the research findings. To provide a thorough and well-rounded understanding of the research topic, triangulation involves integrating multiple sources of data or methodologies. A few data collection techniques were used to implement triangulation. This included methods for gathering both qualitative and quantitative data, like surveys and interviews. These techniques were chosen to record various and complementary insights into different aspects of the intervention's effectiveness and feasibility. In order to fully comprehend participants' experiences, perceptions, and attitudes towards the co-designed intervention, interviews were used as the qualitative data collection technique. By highlighting potential obstacles, facilitators, or areas for improvement, participants were able to offer rich, nuanced insights into the feasibility of the intervention using this method. In order to gather quantifiable information on participants' acceptance, satisfaction, or adherence to the intervention, questionnaires were used as the quantitative data collection technique. These measurements offered quantitative information that could be analysed, providing a more impartial viewpoint on the feasibility outcomes. The information gathered using various techniques was then compared and examined in an organised and integrated manner. The study was able to find patterns, discrepancies, or convergences across various data sources by triangulating the qualitative and quantitative findings, which enhanced the overall rigour and comprehensiveness of the feasibility results. Additionally, the use of various data collection techniques allowed for a more thorough understanding of the co-designed intervention's feasibility and offered insights into potential effectiveness. By correlating or contrasting data from various sources, it helped to validate the results while lowering the risk of bias or overreliance on a single data type. Overall, the final study's triangulation strategy made it possible to assess the co-designed intervention's feasibility with greater rigour. The study improved the validity of the findings and increased confidence in the conclusions and recommendations made regarding the feasibility of the intervention by incorporating a variety of data sources and methods.

2.7 Trustworthiness and rigour in qualitative research

The fundamental principles of qualitative research are anchored in the concepts of trustworthiness and rigour. These principles ensure the credibility, transferability, dependability, and confirmability of the research, serving as qualitative parallels to the notions of validity and reliability in quantitative research. This section will delve into the fundamental principles of trustworthiness and rigour in qualitative research. The section aims to examine the fundamental constituents that enhance the robustness of qualitative research. This section also articulates the significance of meticulous data collection, thorough data analysis, and diligent researcher reflexivity in maintaining the rigour of qualitative research. By understanding and implementing these principles - specifically credibility, transferability, dependability, confirmability, and a thorough approach to data collection, analysis, and researcher reflexivity -, researchers can strengthen the quality and impact of their qualitative studies. The primary objective of this section is to provide a comprehensive framework that ensures the trustworthiness and rigour of qualitative research conducted within the context of this PhD thesis. Researchers can improve the accuracy of their findings and make significant contributions to their fields by adapting and implementing these principles and strategies to their unique research settings, thereby mitigating potential biases.

The trustworthiness or rigour of a study refers to the level of confidence in the data, interpretation, and methodologies employed to guarantee the quality of a study. (115) Trustworthiness is subdivided into credibility, transferability, dependability and confirmability. The idea of trustworthiness, as defined by Lincoln and Guba, assumes a vital role in raising the value and credibility of a research study in the field of qualitative research. (116) Numerous factors that affect the validity and dependability of the results are incorporated into the concept of trustworthiness. Credibility is mostly about establishing trust in the accuracy and reliability of the study findings. Transferability examines how easily and meaningfully the research findings can be used in various contexts or situations. Dependability refers to the consistency and stability of the research method and conclusions. Last but not least, confirmability refers to the degree to which a study's conclusions are influenced by the participants themselves as opposed to the researcher's biases, motivations, or interests. (117) Table 1 provides a comprehensive overview of the quality criteria used in the studies of this thesis to ensure rigour and trustworthiness. It presents the means of enhancing credibility, transferability, dependability, and confirmability in the studies. It also outlines the specific actions taken, such as member checking, providing detailed contextual descriptions, maintaining an audit trail, and adopting reflexivity to uphold these criteria and bolster the validity of the study findings.

Table 1. Quality criteria and trustworthiness in the studies of this thesis

Quality Criteria	**Ways to increase rigour**	**Methods employed in the studies of this thesis**	**Specific Actions Taken**
Credibility	Transparency, researcher's expertise, strict data gathering and analysis methodologies, member checking	Applied thorough data-gathering methods and performed member checks to validate the accuracy of the identified stages, ensuring that findings resonated with participants' perspectives	Used member checking to validate identified stages, allowed participant feedback to refine the findings
Transferability	Providing background, extensive description, interpretive insights, thick contextual description	Offered detailed background and context of the study, provided detailed descriptions of findings, employed the technique of thick contextual description, capturing the cultural, social, and personal factors that influenced the design process	Utilised thick contextual description to capture the influences on the design process, enabled participant involvement in intervention design
Dependability	Explicit description and documentation of the research processes, data sources, analysis tools, audit trail, referential adequacy	Maintained a clear audit trail of all research processes and decisions, documented data sources, cross-referenced findings with existing literature	Kept detailed documentation and audit trails of research steps and decisions, referred to existing literature to reinforce findings
Confirmability	Adopting a reflective perspective, addressing potential researcher influence, using methodical techniques for data processing and interpretation, reflexivity and transparency	Engaged in reflexivity, explicitly acknowledged potential biases and addressed them, maintained transparency in data analysis and interpretation	Embraced reflexivity to minimise researcher bias, peer debriefing for critical analysis of data and interpretations

Prolonged engagement and persistent observation techniques were used to establish trust and capture detailed accounts of the process. Member checking was employed to validate the accuracy of the identified stages, ensuring that the findings resonated with participants' perspectives. Triangulation was achieved by incorporating multiple focus groups to capture diverse experiences and perspectives, strengthening the reliability and validity of the process map. In the second study, the technique of member checking was employed. The participants were actively involved in the design process, sharing their experiences, needs, and preferences. Their input was sought at various stages, ensuring that the intervention was tailored to their specific context. Through iterative feedback and discussions, the participants validated and refined the intervention, enhancing its relevance and applicability. The technique of thick contextual description was also employed, capturing the cultural, social, and personal factors that influenced the design process, contributing to the comprehensive understanding of the co-design process. In the final study, peer debriefing played a vital role, as researchers engaged in discussions with fellow experts to critically analyse the collected data and interpretations. Negative case analysis was employed to identify potential challenges and limitations of the intervention, ensuring a comprehensive evaluation. The audit trail technique was implemented, documenting the research steps and decisions made throughout the study, enhancing the transparency and traceability of the evaluation process. Lastly, reflexivity was embraced to acknowledge and minimise potential researcher bias, ensuring the objectivity and rigour of the evaluation.

Chapter 3

3. Mapping the experiences of people with achalasia from initial symptoms to long-term management

Chapter 3 presents the publication:

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3.1 Introduction

Achalasia is a rare motility disorder affecting the oesophagus. For those diagnosed, it represents a significant shift in their quality of life and daily experiences. This manuscript explored the multidimensional experiences of people living with achalasia, emphasising dimensions not typically addressed in standard medical literature. Chapter 3 identifies a deficiency in the extant medical framework. While traditional clinical approaches offer crucial understanding regarding the physiological presentations of achalasia, they frequently do not encompass the broader experiential, psychological, and sociocultural issues associated with the disorder.

To elucidate these dimensions, a qualitative methodology was utilised. Through process mapping, this chapter outlines the intricate pathway patients navigate – from the initial emergence of unfamiliar symptoms to the complexities of diagnosis, the expectations and concerns associated with therapeutic interventions, and the ongoing considerations of long-term management. The resultant narrative underscores not merely clinical challenges but also systemic obstacles such as prevalent misdiagnoses, delays, and a notable lack of long-term support.

This qualitative analysis provides a comprehensive examination of the challenges associated with achalasia, emphasising the perspectives of individuals directly impacted by the condition, and offers an in-depth overview of the people's experience within this disorder. By grounding the research in the first-hand accounts of people living with achalasia, this chapter contributes to a foundation for more patient-centred research methodologies and care protocols. It also introduces an in-depth and comprehensive viewpoint to the existing literature on achalasia. This analysis positions the chapter as a pivotal component in the integrated framework of comprehensive achalasia care.

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ORIGINAL RESEARCH PAPER

WILEY

Mapping the experiences of people with achalasia from initial symptoms to long-term management

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Abstract

Background: Achalasia is a rare motility disorder affecting the oesophagus, which is associated with a range of symptoms and different treatment strategies. Currently, little is known about people's experiences with achalasia and its management. This study aimed to understand the experiences of people living with achalasia, from the initial onset of symptoms to long-term management.

Method: This qualitative study explored the journey of people living with achalasia and outlined the care pathway using a process map. Ten female and five male participants living with achalasia (age range: 40-73) took part, and all aspects of their diagnosis, treatment and management were discussed. A process map showing people's experiences by separating the management of their condition into a series of steps was developed to present the pathway in the participants' journey. The analysis involved discussing the process map within the research team.

Results: The process map comprised of 10 steps, which occurred before and after diagnosis. The developed map indicates that most participants managed their on-going symptoms through stress management techniques and dietary changes. Key issues that participants highlighted about their journey managing achalasia were misdiagnosis, delay in diagnosis and lack of support in the long-term management of achalasia.

Conclusions: This research was a novel study exploring patients' experiences and management of achalasia and mapping their journey. Two distinct phases to their journeys were identified: before and after diagnosis. Areas highlighted by this study can provide a basis for future research, in particular behaviour change to support the long-term management of achalasia.

KEYWORDS

Achalasia, chronic condition, diet, patient experiences, process map, rare condition, self-management, stress

1 | INTRODUCTION

Achalasia is a rare motility disorder affecting the oesophagus. This condition can start at any time of life but is more common in middle-aged or older adults.[1] It is equally prevalent in males and females, with an overall incidence of 1.63 cases per 100 000 people.[2,3] The underlying causes of achalasia are unknown.[1] Characteristic features, such as a non-relaxing sphincter, weak or absent oesophageal peristalsis and simultaneous or poorly coordinated contraction, lead to an outflow obstruction at the level of the lower oesophageal sphincter (LOS). The presence of these features leads to difficulty in swallowing, particularly with liquids before solids, as well as a variety of other associated symptoms. Patients can present with several years' history of progressive symptoms, or acutely with a range of symptoms such as complete dysphagia, regurgitation and progressive weight loss.[1] The symptom onset is typically insidious and usually progress over many years, and it has a substantial impact on quality of life.[2] The diagnosis of achalasia can be confirmed by different diagnostic tests such as endoscopy, barium swallow and manometry.[1] Despite it being a crippling condition, about 20-50% of cases are initially misdiagnosed, with patients given an alternative diagnosis such as gastro-oesophageal reflux disease or hiatus hernia.[4] Treatments for achalasia are often delayed due to a lack of diagnosis, and even the most effective treatments usually do not achieve a cure.[2] Therefore, in a large proportion of patients, the initial treatment is either delayed or inappropriate and ineffective.[5] Moreover, as the cause of achalasia is unknown, treatment has focused on alleviating the symptoms and their consequences. There are different treatment options available for achalasia such as medications, Botox injections, balloon dilatation, surgical interventions and non-medical interventions such as behavioural changes. It is therefore critical that people with achalasia learn to self-manage their symptoms (to some degree).

Behavioural and lifestyle adjustments are required for successful management of chronic conditions.[6] Chronic disease management is typically conducted by the patient in their day-to-day life; however, their interaction with health-care providers is a critical intersection for information exchange, decision making and motivation.[7] Chronically ill patients have to manage their daily living under different financial and social constraints, and their associated symptoms can complicate the most routine activities of daily living.[7] According to a study carried out by Clark et al,[8] three separate categories of activities need to be addressed in order to successfully self-manage a chronic condition.[8] First, people with chronic conditions need to have an adequate knowledge about their condition and its treatment to make informed decisions. Second, they need to perform activities in order to manage their condition by making changes to their lifestyle, including changing their dietary habits. Third, they need to apply skills to maintain adequate psychosocial functioning, which includes working, maintaining a good family life and cultivating social relationships.[8] These self-management activities aim to reduce the impact of chronic conditions on daily life.

It is challenging to live with any chronic condition, in particular a rare disease such as achalasia. The general public often shows sympathy and understanding when someone lives with a visible or well-known disease; however, living with a rare or less visible disease generates different challenges for individuals and those who interact with them.[9] Knowledge, coping strategies and problem-solving skills are factors that enhance adjustment and adaptation to a long-term chronic condition.[9] A better understanding of their condition helps people to cope with the anxiety and uncertainty, while lack of knowledge leads to a sense of powerlessness.[10]

Health-care professionals who do not have the knowledge to diagnose a rare disease may mistakenly label their patients as 'psychological cases' rather than persons having an individualized physical illness.[9] This is demonstrated in results from the study of another rare condition, scleroderma, in which nurses with very little knowledge about this rare condition stigmatized individuals by ignoring the signs and symptoms of the condition and labelling them as 'untrustworthy'.[9] Stigma can produce a sense of fear and rejection among people with such a health condition.[9] This is further evident historically where, for example, people with epilepsy were stigmatized as dangerous or violent due to a lack of knowledge amongst the general public.[6]

Exploring people's experiences can be a valuable way of providing first-hand information about their care pathways. There is often a lack of appropriate health services, effective treatment options and skilled health professionals for rare conditions.[11] Patients can be the best source of information to give appropriate suggestions relating to their experiences and areas of their care which need improvement.[11] Rare diseases have a significant psychological and emotional impact on patients and their families, which is often followed by a lack of appropriate community and peer support.[11] Research has explored different treatment options for achalasia in terms of their effectiveness, but the focus has not been on the patient's experience and in particular the individual's journey along their pathway. The current study thus aimed to map the experiences of people living with achalasia from diagnosis through to long-term management and to suggest where further input is needed from health-care professionals.

2 | METHOD

2.1 | Design

An exploratory qualitative study using a process map was conducted. Quantitative studies such as surveys were not appropriate as this was exploratory work. The data provided in the mapping sessions can be used to improve patient pathways.[12] This study involved in-depth, semi-structured mapping sessions to explore and understand the care pathways for people living with achalasia and the long-term management of this condition. This study used a phenomenological approach to describe the lived experiences of people with achalasia [13] and allow the researcher to understand and gain rich details on an unknown area.

2.2 | Methodology

This study involved three mapping sessions, which were conducted in London, United Kingdom. The research materials, including the topic guide and draft map, were prepared by the research team before each session. A process map was produced in each session, and information was added cumulatively. The process map produced in the final session included all the steps involved in the participant journey, which was discussed in the three sessions from the first onset of the symptoms through to the on-going management of achalasia. The final process map was discussed and refined within the research team. A favourable ethical opinion was granted through the University of Reading Research Ethics Committee (UREC-13/38).

2.3 | Paradigm underpinning the methodology

Constructivism was the approach used to interpret the data that were collected in the sessions. This approach considers that there could be multiple interpretations of an event, shaped by the researcher's historical or social perspective in comparison with positivism, which adheres to the factual knowledge gained through observation and measurements.[14] This research was a qualitative study to understand a particular phenomenon; therefore, data were interpreted based on the researcher's expertise.[14] In this approach, it is acknowledged that the researcher interprets the data based on their own understanding and knowledge developed through their own experiences.[15] The researchers facilitated the sessions using prompts to elicit the participants' experiences. Through the analysis, the researchers constructed meaning from the data based upon their previous knowledge and research to produce the final process map.

2.4 | Recruitment

Participants were recruited through the Achalasia Support Group affiliated with Achalasia Action, an independent charity supporting people living with achalasia in the United Kingdom (UK). This is a national group, with over 400 members, based in London and run by members of the public living with achalasia. People usually find and join this group through searching on the Internet and word of mouth. Convenience sampling was the strategy used to recruit participants based on their willingness and availability to take part. The inclusion criteria for this study were as follows: anyone living in the UK, aged 18 years or over, with a confirmed diagnosis of achalasia, who consented to take part, was able to attend a session and spoke English. The researcher emailed the recruitment materials, which included an information sheet and consent form, to the administrator of the support group who distributed these through the support group mailing list inviting members to participate. Participants were asked to contact the researcher (MK) with their interest in taking part in a mapping session.

2.5 | Data collection

Before the first session, a basic draft of a process map was produced by the researcher based on preliminary research,[16] which involved interviewing individuals living with achalasia about their experiences. Based on the preliminary research, the draft process map consisted of three main stages, which were pre-diagnosis, diagnosis and after diagnosis to facilitate discussion in the mapping sessions. The draft process map was used to provide structure to the discussion.

2.6 | Process mapping sessions

Participants in the current study were allocated to one of the three mapping sessions based on their availability. Mapping sessions were held over a month with a maximum of eight people in each session. The aim of the study, the structure of the session and the topics for discussion were stated at the beginning of each session. The ground rules were explicitly stated and included confidentiality, raising concerns during sessions and the option to withdraw from participation. After their consent had been obtained at the beginning of each session, participants were given a brief demographic questionnaire asking their sex, age, living status (living alone or co-habiting) and the type of medical interventions they had received for achalasia. The sessions lasted around 90-120 minutes and were audio-recorded for accuracy check purposes.

In each session, participants were asked to talk through their journey from the first onset of their symptoms through to the on-going management. The researchers provided prompts to participants and recorded their experiences. Two researchers were present at each session to ensure all the points that were raised were documented. At the end of each session, the researchers checked all points raised were documented and then participants were provided with stickers to add to the discussion board to highlight the most challenging steps in their journey. The collected data in the mapping sessions produced a process map, and the recordings were used for accuracy check purposes only. Participant quotes were not transcribed and included in the process maps as the main aim of this study was to explore the overall care pathways and steps involved in people's journey living with achalasia. In this methodology, data are collected in real time and a process map is created in the mapping sessions. Two female researchers facilitated each session. Session 1 was run by two pharmacist researchers, and the following sessions were run by a pharmacist and a health psychologist.

2.7 | Data analysis

The collected data were discussed within the research team after each session. The content with similar ideas or concepts was grouped and then assigned headings corresponding to key steps in people's journeys, resulting in a more detailed and informative draft map for the second session. The process map and its contents were edited and analysed through listening repeatedly to the recordings. Recordings were reviewed to check the accuracy of the process map, and they were listened to repeatedly to identify the steps and the iterative process of people's journeys. Findings were analysed by the research team to address the aim of the research. The analysis involved discussing the findings based on the number of steps in their journey, number of times the patients had been sent from one health-care professional to another, time taken in and between each step, steps that added no value for the participants and areas where problems were raised for them.[17] Through this analysis, process map was developed and validated by the participants in the final session where participants were asked to confirm whether the process map was an accurate representation of their journey. Data saturation was achieved in the final session. Data saturation is reached when there is enough information to replicate the study and when the ability to gain additional new information has been attained.[18] The final process map is the end product of the analysis, and it gives an outline of the findings. The researchers created the final process map iteratively by analysing the constructs in detail to develop a map that most accurately represents the participants' journey. The final developed process map presents the discrete steps in a participant's journey in the order in which they occurred.

3 | RESULTS

3.1 | Sample

This study included 15 participants (5 males and 10 females) with achalasia. The participants ranged in age from 40 to 73 years (mean 56). One person contacted the researcher and then decided not to take part due to the group setting involved in the mapping session. Most participants were white British, and living with a partner, family or friend (co-habiting) (see Table 1 for demographic details of the participants). Disease management reported by participants ranged from a year to 20 years. Two participants participated in session 1, eight in session 2 and five in session 3.

3.2 | Overview of findings

Participants provided rich insights into their journey living with achalasia. Figure 1 shows the key steps in the participants' journeys. The results show that there were two main phases (before and after diagnosis) with 10 steps in total. These steps were as follows: 1. symptoms; 2. management; 3. seeking medical help; 4. diagnosis based on the symptoms experienced; 5. return to GP; 6. sent for tests; 7. offered treatments; 8. post-treatment complications or symptoms; 9. on-going management; and 10. general impacts. These steps were the headings used in the mapping sessions and provide the structure for this results section. The process map created after the three sessions was the end product, and the rich details led to developing the process map. Similarities were identified amongst participants' responses in the onset of the symptoms, the tests they received for diagnosis and the treatments offered. Key issues that participants highlighted included the initial misdiagnosis, the delay in receiving the diagnosis and the lack of additional support throughout their journey. Figure 1 is the final version of the process map, illustrating a summary of the participants' journey with achalasia from the first signs and symptoms through to on-going management.

TABLE 1 Participants' demographics

Participant's demographics	All participants (n = 15)	
Sex	Male	n = 5 (33%)
	Female	n = 10 (67%)
Age (years)	Mean (SD)	56.2 (13.3)
	Range	40-73
Ethnicity	White	n = 15 (100%)
Living status	Living alone	n = 4 (27%)
	Co-habiting	n = 11 (73%)
Employment status	Full time	n = 5 (33%)
	Part time	n = 3 (20%)
	Retired	n = 5 (33%)
	Not working	n = 1 (7%)
	Not stated	n = 1 (7%)
Medical treatment	Multiple treatments (medication and/or surgery)	n = 4 (27%)
	Single treatment	n = 8 (53%)
	No treatment	n = 2 (13%)
	Not stated	n = 1 (7%)

3.3 | Before diagnosis

Apart from a few participants who visited a private health-care professional, the majority of the participants visited their National Health Service (NHS) general practitioner (GP). Due to the similarity of the symptoms of achalasia to other conditions, participants were often given treatment for another condition, which was unsuccessful. They became stuck in a loop where they had to repeatedly visit their NHS GP until being sent for an appropriate test and referred to a specialist for diagnosis. Participants who visited a private health-care professional reported obtaining a diagnosis quicker as they were sent for the appropriate diagnostic tests immediately.

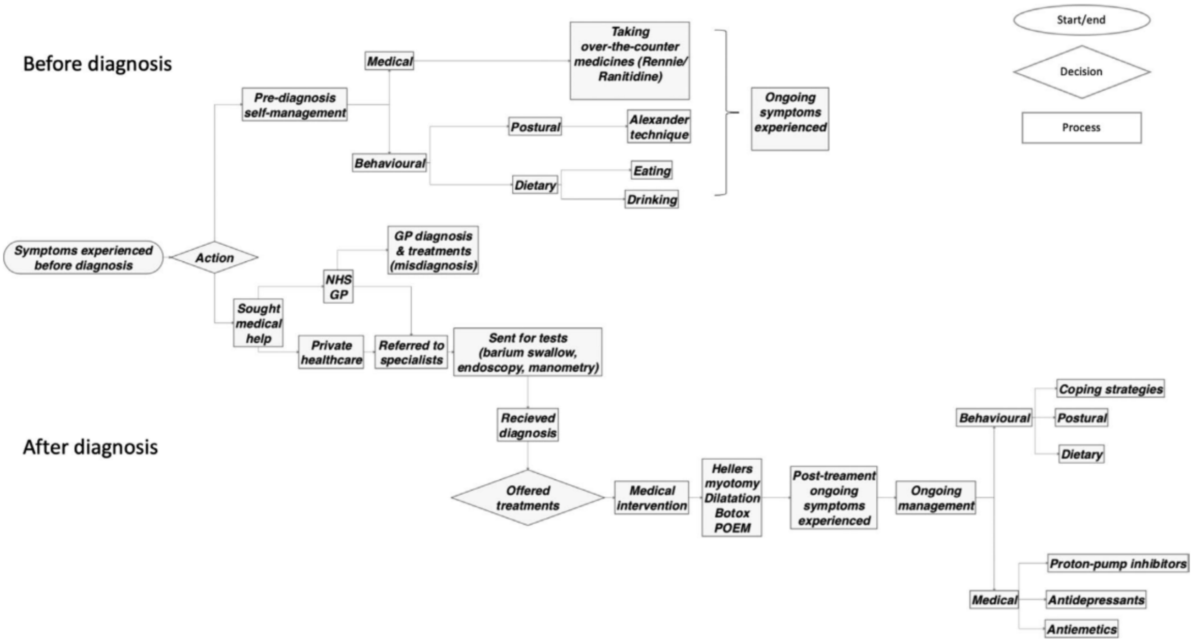

FIGURE 1 Process map of participants' journey

3.3.1 | Symptoms experienced by participants before diagnosis

The majority of participants experienced a range of symptoms initially, such as chest pain, regurgitation, difficulty swallowing and heartburn. Some also reported experiencing recurrent burping, breathlessness and choking.

3.3.2 | Pre-diagnosis management

After initially experiencing symptoms, people with achalasia took two different routes, with some seeking medical help to find out the underlying cause of their symptoms and the rest taking actions to self-manage their symptoms. Some people tried to manage their symptoms by buying over-the-counter medicines, including indigestion remedies such as Rennie or Ranitidine. Some addressed them indirectly simply by adjusting their diet unconsciously and eating what they found easier to swallow. One participant reported 'googling' her symptoms to find the underlying cause.

3.3.3 | Seeking medical help

After attempting to self-manage their condition, participants reported seeking medical help and visiting their GP when there was no improvement in their symptoms and the symptoms persisted. The majority of participants visited their GP through the NHS to obtain a diagnosis. Other participants, however, sought medical help through their private medical insurance. Those who went to a private health-care professional reported getting a diagnosis earlier than those who accessed a GP via the NHS.

3.3.4 | Misdiagnosis and treatment

Symptoms experienced by people with achalasia are very similar to other conditions; therefore, it was often misdiagnosed. Aortic aneurysm, acid reflux, angina and hiatus hernia were a few common conditions that people were diagnosed with at their many visits to the GP. They were getting treatments for these conditions but had to go back to their GP repeatedly due to on-going issues such as not being able to eat or drink, experiencing painful spasms and losing weight.

3.3.5 | Return to GP

Participants revisited their GP many times before being referred to a specialist and sent for appropriate tests to get a diagnosis. One of the participants reported having to demonstrate how she struggled to swallow water before being sent for tests. After multiple visits to their GP, participants were eventually referred to address their symptoms. The initial referral varied, with participants, referred to an oncologist, ENT (ear, nose and throat) specialist or gastroenterologist or sent directly for tests.

3.3.6 | Sent for tests

The common tests which almost all participants were sent in varying order included barium swallow, endoscopy, manometry and computerized tomography (CT) scan. After undergoing several tests, participants reported receiving a diagnosis and being offered treatments to choose from.

3.4 | After diagnosis

Once participants obtained a diagnosis, they were offered a medical intervention, such as endoscopic Botox injection, endoscopic balloon dilatation or laparoscopic Heller's myotomy. Participants either chose to undergo a procedure or manage their condition with non-medical interventions (such as dietary changes). Once participants had an understanding of the condition, they attempted to self-manage. Participants had to change their dietary habits, such as the timing of their meals or choosing foods that were easier to swallow, and also tried changing their posture at night by sleeping in a more upright position. At this time, participants had a few options, including choosing one or more treatments, managing their condition by behavioural changes, accessing information about their condition, and joining an online support group to get more help. They also reported issues such as struggling to find accurate information on the management of their symptoms and insufficient support from the health-care team after diagnosis.

3.4.1 | Offered treatment

Only one participant reported a significant delay in communication receiving a diagnosis from her GP after the diagnostic tests. Many reported that health-care professionals offered only endoscopic or surgical treatments, instead of any lifestyle or behavioural changes that could have benefited them in the on-going management of their condition. Participants also emphasized a lack of support and communication from health-care professionals at this stage. Most of the participants were not satisfied with the level of information provided about the treatment options from the clinicians, or with the aftercare they received from the nurses at the hospital they visited. Only one participant reported managing their condition with no further medical or surgical treatment.

3.4.2 | Post-treatment complications or symptoms

Participants, in general, complained about the lack of follow-up and monitoring after treatment. They believed they were more susceptible to illnesses due to inability to consume nutritious food. Almost all participants reported that the treatments did not resolve their symptoms completely and that they were still experiencing symptoms such as heartburn, indigestion and pain. Some participants experienced repeated treatments, whereas others continued to self-manage their symptoms. At this stage, self-management included taking over-the-counter products such as indigestion remedies (eg Gaviscon), exercise (eg tai chi and yoga) and dietary changes.

3.4.3 | On-going management

Participants sought to manage their condition through self-management, using behavioural and medical strategies. Some participants reported changing behaviours such as their diet and lifestyle, while others were taking therapeutic medicines such as anti-depressants and cannabis oil to cope with their condition. The majority of participants used a combination of strategies to reduce the recurrence of symptoms. Almost all reported educating themselves by searching online and communicating with other members of the online support group. The on-going management of their condition was reported as one of the most crucial points in the journey, as support was required in the long-term.

3.4.4 | General impacts on day-to-day living

Participants referred to achalasia as a hidden disability, an unseen illness that has a significant impact on social life and employability. Achalasia significantly affected their lives, and they reported feeling anxious, stressed, exhausted and depressed, which meant they could not perform their daily tasks as they would have liked.

4 | DISCUSSION

This is the first study to the authors' knowledge that explored people's experiences of living with achalasia using a process map. People living with achalasia experience a complicated journey from seeking a diagnosis through to post-diagnosis. The complexity of their journey is mainly due to the ambiguity of symptom presentation, lack of knowledge from doctors and the rarity and chronic nature of the condition. There is no one way to manage the symptoms of achalasia; therefore, people living with this condition need to manage their symptoms by trying different self-management strategies through trial and error. The key findings of this study were the steps involved in people's journey living with achalasia and the areas in their journey which participants found difficult. These key areas were the delayed diagnosis and the difficulties they experience in the on-going symptoms management, specifically the lack of support from health-care professionals involved in their care. These were the areas where an intervention could be implemented to help them in the on-going long-term management of this condition. This study also highlighted the lag in the initial stages where people with achalasia are misdiagnosed, and they make multiple visits to the doctors to receive a diagnosis. The key message of this novel study is despite different successful evidence-based medical interventions people living with achalasia continue to experience symptoms, such as reflux and pain, and have to self-manage their condition. This is a potential area that an intervention could be developed and implemented to support the on-going long-term management of achalasia.

Before receiving a diagnosis, people had to deal with uncertainty and anxiety. Furthermore, as they did not know what they were living with, the lack of knowledge about their condition led to a feeling of helplessness. Most were stuck in a loop of obtaining a misdiagnosis, with treatment directed towards the symptoms based on the erroneous diagnosis. Many discussed how not knowing about the condition and its underlying causes and treatments made them anxious. Continued uncertainty about a condition can affect the quality of life, for example by increasing levels of depression and emotional distress.[19] Mishel et al defined uncertainty as to the inability to determine the meaning of illness-related events which arises when there is a lack of information to understand one's illness, treatment and side-effects.[20] They also defined uncertainty as to when individuals are unable to use health-care professionals or related support to obtain knowledge which they need in order to develop a strategy for coping with an unfamiliar situation.[20] Our empirical for achalasia patients are consistent Mishel et al theoretical account of uncertainty. In chronic conditions, the experience of uncertainty spreads to wider life issues. Familiar routines are disrupted and perceptions of the order of life are altered.[21]

Self-management was a common approach in all the steps involved in the journey of patients with achalasia from before diagnosis to after treatment. Participants described a range of self-management strategies, including medical and behavioural adjustments, such as dietary changes, to cope with their condition, even though some had undergone successful medical or surgical treatments. Achalasia patients need to self-manage as do people with other chronic conditions as shown in previous research. Corbin and Strauss suggest three self-management tasks for chronic illnesses: behavioural management (adjusting lifestyle), emotional management (managing anger, fear or frustration) and medical management (taking medication).[22] They recommend to accomplish these tasks, and people with chronic conditions ought to apply core self-management skills, such as problem-solving, decision making, resource utilization, taking action and partnership with health-care providers.[21] Participants in our study also reported using these core skills to a varying extent through their journey. In a study on HIV, eight main categories of self-management strategies emerged: (a) take medication or treatment; (b) modify activity; (c) alter food in the diet; (d) seek help; (e) wait; (f) substance use; (g) manage thoughts or attitude; and (h) alter physical environment.[23] These self-management strategies were also described by the participants in our study suggesting some core management approaches across disease types.

After diagnosis, participants were offered different treatment options. Their treatment choices were based mainly on the health-care professional's advice and recommendations, along with, to some extent, on the minimal information available to participants regarding treatments. The International Society for Disease of the Oesophagus developed a guidelines in 2018 intending to offer clinicians and patients an up-to-date framework for making informed decisions on the management of this rare condition.[24] Fifty-one experts from 11 countries and three representatives from patient support associations participated in preparing these guidelines. Even though the consensus agreement score of the available treatments was more than 80% and most of the available treatments were considered successful, the majority of patients who participated in developing the guidelines were still experiencing symptoms after undergoing treatment.[24] Achalasia, like many other chronic conditions, requires on-going treatment and continuous self-management as it has no cure and the available treatments serve only to alleviate the symptoms. Patients attempt to use a variety of personal, social and health-care resources to lessen the treatment burden.[25] The results of our study are consistent with other evidence which links social support, optimism and spirituality to better well-being in chronic conditions.[25] Therefore, although the available treatments are reported to be more than 80% successful, they are not 100% effective in all patients. The process map produced in this study maps out the journey of patients and gives an insight to health-care professionals to see what patients go through from the first onset of their symptoms to the on-going management of achalasia. The produced process map can also be a useful decision aid for health-care professionals. Moreover, it can assist health-care professionals for better shared decision making.

4.1 | Strengths and limitations

The mapping process in this study allowed the researchers to receive first-hand and in-depth insight into participants' experiences with this rare chronic condition. Process mapping is a useful method, which has not previously been used to understand patient's experiences living with achalasia by separating the management of the condition into a series of steps allowing the researcher to see the sequence of steps involved in their care pathway. It is an interactive approach that collects ideas from people who are involved in the same process. The data collected for producing the process map can be used to redesign patient pathways and improve the quality or efficiency of management of a disease such as achalasia and alter the focus of care towards activities that are most valued by patients. The nature of this method let participants discuss their journey within a group setting and collect ideas from a group of people, which resulted in the end product of the process map that interviews alone would not allow. Participants were asked to talk about their journey from before diagnosis through to the on-going management, with further details added in each session. People in the last session confirmed that the developed map was an accurate representation of their journey. The current study explored a rare condition using qualitative methods to gain an insight into the steps involved in people's journey. The process map provides structure and enables evaluation of the steps involved in their journey.

There were several limitations to this research. Although the sample size was small, it was appropriate for the method used[17]; future research may use a quantitative approach such as questionnaires to access the experiences of people with achalasia outside the UK in a larger scale. Participants were recruited through a support group, which provides the opportunity for its members to share experiences and tips with others; their on-going disease management may, therefore differ from that of people who are not part of such a support group. People were asked to attend and engage in an in-depth mapping session and share sensitive information about a significant period in their lives, and this could affect how they reported certain events. The voluntary nature of participation meant that people who took part may have had a different experience to others who are not willing to participate in research. The results presented in this paper are solely based on what was described in the sessions and the interpretation of the researchers, and its findings should, therefore, be viewed from that perspective.

With regard to credibility, the multidisciplinary background of the research team enables us to explore different perspectives while interpreting the data. We used convenience sampling in order to make sure that the selected participants were representative of the variety of views and background to ensure the transferability of results.[26] The findings from this study are representative of a white, mainly female, adult sample who live in the UK and were able to speak English. Theoretical saturation was achieved through the three mapping sessions; therefore, data collected was stopped as no new information was added to the process map.

4.2 | Implications for practice and research

The findings from this study have implications for both clinical practice and future research. The process map produced in this study maps out the journey of patients and gives an insight to health-care professionals to understand what patients go through from the first onset of their symptoms to the on-going management of achalasia. It also provides new insights into the patient's journey from the patient's perspective, which could be used to improve the doctor-patient relationship. Understanding the patient's journey from their perspective could enable and encourage health-care professionals to tailor the care of individuals based on their journey and can also be a useful decision aid for health-care professionals. Moreover, it can assist health-care professionals for better shared decision making. The results also identified that participants felt that they did not receive enough information and support throughout their journey and for the long-term management of achalasia. Misdiagnosis by the NHS GPs was also very common. These findings highlight the need to co-develop patient resources to find out what resources, interventions and support patients think they would benefit from, along with further GP training. The results from this study also identified the key time points and the steps where people feel they need additional support. Stress was a key component, which triggered patients' symptoms at different phases, and was highlighted as a potential area for future research. A stress management programme could be developed as a tool in enabling people to deal with the anxiety and stress associated with this condition.

4.3 | Future research

Future studies should design or co-design an intervention with people with achalasia to initiate a behaviour change so it can help people to self-manage their condition better, and further studies should include health-care professionals as co-producers of research knowledge (such as doing research collaboratively as opposed to doing research on people with achalasia) to underpin further work on developing interventions to enable better disease management.

5 | CONCLUSION

This study mapped the journey of people with achalasia. The study highlighted the issues people faced at each stage in their journey and identified the areas that need addressing to help people cope with their condition, including interventions to improve patient care. The process map also highlighted the importance of self-management of chronic conditions. People who participated in this study may have undergone different medical treatments, but all of them were still experiencing symptoms that required them to adopt different self-management strategies to carry out their normal lives.

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We confirm all personal identifiers have been removed so the persons described are not identifiable and cannot be identified through details of their journey. We thank the participants who were involved in this project and Amanda Ladell, the Achalasia Action administrator, for her on-going support.

CONFLICT OF INTEREST

The authors declare no potential conflicts of interest with respect to the research, authorship and/or publication of this article.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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Chapter 4

4. Co-designing an intervention using the COM-B model to change an eating behaviour in people living with achalasia

Chapter 4 presents the publication:

Kalantari M, Hollywood A, Lim R, Hashemi M. Co-designing an intervention using the COM-B model to change an eating behaviour in people living with achalasia. Frontiers. (Submitted in May 2023 to Frontiers - under review)

4.1 Introduction

Building upon the findings from chapter 3, which outlined the complex and multifaceted experiences of people living with achalasia, chapter 4 takes a targeted and novel approach to address a primary concern explicitly identified by the participants. Chapter 3 underscored the diverse challenges faced and the need for enhanced social, clinical, and behavioural support during the long-term management of achalasia.

With the objective of identifying the most challenging eating behaviour and co-designing a targeted intervention, chapter 4 embraced a collaborative approach. Utilising the COM-B model as a theoretical framework and employing online focus groups, this study sought to actively engage people living with achalasia in the development of an intervention tailored to their needs. (see appendix 11)

The 24 participants identified 'eating in a social setting' as the crucial target behaviour. Their insights, combined with theory and evidence, led to the design of the intervention and identified a self-directed workbook as the mode of delivery. Reflecting the constructs of the COM-B model, the workbook incorporates reflection and activities, with behaviour change techniques such as social support, goals and planning.

Chapter 4 not only builds upon the findings of the previous chapter but embodies a pioneering approach to patient-centred research in achalasia. By co-designing an intervention with those it aims to help, this study moves closer to a more empathetic and effective model of care. In focusing on the real-world challenges faced by people living with achalasia and in engaging them as active partners in research, chapter 4 moves toward more personalised and compassionate care. It offers an important contribution to the field, suggesting that the lessons learned here might apply beyond just achalasia. Moreover, it highlights the benefits of collaborative methods in healthcare research.

Title page

Title

Co-designing an intervention using the COM-B model to change an eating behaviour in people living with achalasia

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Co-designing an intervention using the COM-B model to change an eating behaviour in people living with achalasia

Abstract

Background: Achalasia is a rare motility disorder affecting the oesophagus, leading to difficulties with eating and drinking. Participants in previous studies reported that they needed more social, clinical and behavioural support in the long-term management of achalasia. This study therefore aimed to 1) identify the most challenging eating behaviour for people living with achalasia and 2) co-design a behaviour change intervention to help address the challenges they experience.

Methods: This study used a qualitative approach involving online focus groups. The COM-B model was the theoretical framework, with behaviour change techniques (BCTs) as the active ingredients that target a mixture of capability, opportunity and/or motivation. Three focus groups were undertaken to obtain a range of input from different people living with achalasia. Participants in this study identified the target behaviour, prioritised the different BCTs which most resonated with them to design an intervention and decided on the mode of delivery. The research team analysed the techniques that helped participants with their eating behaviour using the COM-B model as a framework to create the intervention.

Results: The 24 participants in this study identified 'eating in a social setting' as the target behaviour for the intervention. A workbook that can be personalised by the individual was the most suitable intervention. The workbook structure aligns with the constructs of the COM-B model. It includes reflection, activities and goal-setting sections based on what was indicated to be useful for the majority of the participants. Key techniques to overcome the challenges with eating in a social setting included social support, regulation to reduce negative emotions, goals and planning.

Conclusion: Using a focus group approach with the COM-B model as the theoretical framework, the participants in this study developed an intervention to support people living with achalasia. In order to achieve long-term behaviour change, engagement with a personalised workbook could facilitate eating in a social setting. Future work will need to pilot the workbook to ensure it can support people to improve their quality of life and complement the ongoing care they receive from health services.

Keywords

Achalasia, co-design, COM-B model, intervention, behaviour change, eating behaviour, chronic condition, rare condition

Background

Achalasia is a rare motility disorder affecting the oesophagus. This condition can start at any time of life but is more common in middle-aged or older adults. (1) It is equally prevalent in males and females, with an overall incidence of 1.63 cases per 100,000 people. (2,3) The underlying causes of achalasia are unknown. (1) Characteristic features of the condition include a non-relaxing sphincter, weak or absent oesophageal peristalsis and simultaneous or poorly coordinated contraction, leading to an outflow obstruction at the level of the lower oesophageal sphincter (LOS). (1) The presence of these features leads to difficulty in swallowing liquids and solid food, and a variety of other associated symptoms such as painful spasms, regurgitation, heartburn and choking. (1) Despite it being a disabling condition, about 20−50% of cases are initially misdiagnosed, with patients given an alternative diagnosis such as gastro-oesophageal reflux disease (GORD) or hiatus hernia. (4) Treatment for achalasia is often delayed due to a lack of diagnosis, and even the most effective treatments are unlikely to be curative. (2) Therefore, in a large proportion of patients, the initial treatment is either delayed or inappropriate and ineffective. (5) Moreover, as the cause of achalasia is unknown, treatment has focused on alleviating the symptoms and their consequences. There are different treatment options available for achalasia, including medication (i.e., muscle relaxants), Botox injections, pneumatic dilatation (PD), surgical interventions, such as laparoscopic Heller myotomy (LHM) and peroral endoscopic myotomy (POEM), and non-medical interventions, such as behavioural changes. As treatment options do not provide a definitive cure, it is, therefore, critical that people with achalasia learn to self-manage their symptoms (to some degree).

There are several behaviours that can trigger symptoms in achalasia. Eating behaviours were one of the main problems that were reported by participants in a previous study. (6) In this study, people living with achalasia were interviewed to explore their experiences and management of the condition. Different eating behaviours, such as the type of food, time of the meals and unhealthy eating, such as grazing, were identified as behaviours that exacerbate their symptoms in the ongoing management of achalasia. (6) This highlights that people living with this chronic condition need to make daily decisions about their illnesses. This ownership of managing a chronic condition introduces a new paradigm which involves collaborative care and self-management education. This approach supports people to have the best possible quality of life with their chronic condition by adopting a new paradigm of care. Self-management education teaches problem-solving skills. Self-efficacy, which is a central concept in self-management, gives the patient the confidence to carry out the necessary behaviours in order to reach the desired goal. (7) According to the study carried out by Michie et al. (2013), behaviour changes are facilitated by the 93 active ingredients of the behaviour change technique taxonomy. (8) These techniques include goal setting and provision of instructions. (9) The behaviour change wheel (BCW) is a framework that promotes a systematic method of intervention development. (9) At the core of the BCW framework is a theoretical model called the COM-B model. Based on the COM-B model of behaviour by Michie et al. (2011), individuals should have the physical and psychological capability, opportunity and motivation in order to perform a behaviour. (9)

The current study used an intervention co-design approach using the COM-B model as the structure in order to develop an intervention to change eating behaviours in people living with achalasia. This model is useful to develop a behaviour change intervention not only as it provides a systematic approach to develop an intervention but also enables and ensures transparency. (10) The Theoretical Domains Framework (TDF) is a framework that provides a theoretical lens through which to explore influences on behaviour and provides guidance on identifying behaviour change techniques. The co-design approach is a participatory approach for designing interventions which involves people who live with the condition and are, therefore, experts on the specific behaviours and challenges that affect daily living. The current study thus aims to co-design a behaviour change intervention with people living with achalasia, and in order to do that a specific behaviour should be targeted. Previous research has identified several eating behaviours of concern; therefore, the focus of this study is to prioritise the most challenging eating behaviour and co-design a behaviour change intervention with people living with achalasia.

Methods

Design

This study involved a co-design approach to design an intervention with and for people living with achalasia. This approach is beneficial in order to get first-hand information from people living with the condition and use their experiences to develop an intervention. It also allows people involved in the co-design process to reflect on their experiences of a particular subject and work together to identify improvement priorities, implementing changes, and then jointly reflecting on their achievements. (11) A favourable ethical opinion was granted through the University of Reading School of Chemistry, Food and Pharmacy Research Ethics Committee (SREC 40/2020).

Procedure

The study design for this research was focus groups. A focus group is ideal when discussing a topic with a selected group of people, as it helps to obtain several perspectives about the same topic. Homogeneous groups provide a relatively safe place for participants to share their experiences and, in the case of medical education research, mitigate the power imbalance between researcher and researched by utilising the naturally existent peer group. (12) This design allows the researcher to explore the degree of consensus on a given topic and gather a larger amount of information in a shorter period of time. (13)

The focus groups were conducted online using Microsoft Teams, which is a videoconferencing platform. The aim of the first focus group was to discuss eating behaviours that related to achalasia, identify the target behaviour for the intervention and discuss techniques to change that specific eating behaviour. Participants in the first focus group were presented with a list of behaviours (identified from previous research[6]) and were asked to identify the most challenging one. The eating behaviours included: the time of the meals, types of food, food avoidance, grazing, binge-eating, eating when stressed and eating in private/public. The second focus group aimed to co-design an intervention targeting the identified eating behaviour using the COM-B model as the theoretical framework. The third focus group verified the co-designed intervention and determined the best delivery method for that intervention. The research materials, such as a presentation for each session, were prepared by the research team before each focus group. The TDF was used to create a topic guide with prompt questions. The TDF mapped onto the overarching COM-B paradigm, which provided structure to the focus groups. Figure 1 shows the link between BCT, TDF and the COM-B. The presentation included a background of the targeted behaviour and each element of the COM-B model with examples in order to help participants to discuss the prioritised eating behaviour, which was the aim of the study. The presentation was used as a topic guide to facilitate discussions in the focus group. Participants were asked to discuss the techniques presented to them within each component of the model and discuss what might work best for them in order to change the targeted eating behaviour. Participants in the final session confirmed the researchers' interpretations from the other two sessions and decided on the delivery method of the co-designed intervention. After the focus groups, details of the co-designed intervention and its delivery method were discussed within the research team. The information provided in the focus groups was categorised into different elements of the COM-B model and refined within the research team.

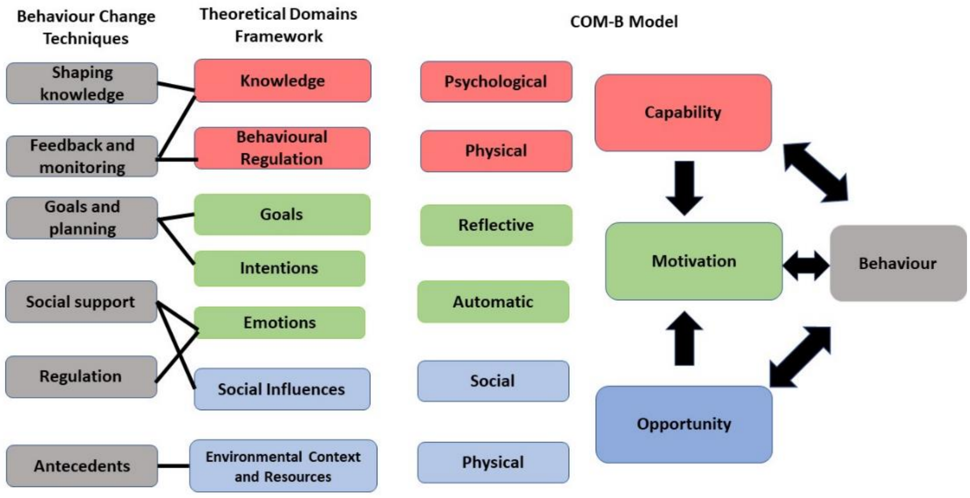

Figure 1. Link between BCTs, TDF and COM-B model

Recruitment

A sample of 24 people living with achalasia were invited to take part in this study. The researcher emailed the recruitment materials, which included an information sheet and consent form, to the administrator of the support group. The Achalasia Support Group is affiliated with Achalasia Action, which is an independent charity supporting people living with achalasia in the United Kingdom (UK). (14) The administrator distributed the study materials to potential participants using the support group mailing list. This is a national group, with over 400 members, based in London and run by members of the public living with achalasia. People usually find and join this group through searching on the Internet and word of mouth. Convenience sampling was the strategy used to recruit participants based on their willingness and availability to take part. Participants were asked to contact the researcher (MK) if they were interested in taking part in a focus group. They were then asked to complete an online consent form followed by completing an online demographic questionnaire asking their sex, age, living status (living alone or co-habiting) and the type of medical interventions they had previously received for achalasia. The inclusion criteria for this study were as follows: anyone living in the UK, aged 18 years or over, with a confirmed diagnosis of achalasia, who consented to participate, was able to join one of the online sessions and spoke and understood English. Participants were only allowed to join one focus group, and they were signed up to their preferred time slot using a Doodle poll, which is a web-based scheduling tool. Utilising different participants across the three focus groups was intentional to enhance the rigour of the study. By engaging with a diverse range of individuals, we aimed to gather a broader spectrum of experiences and perspectives related to achalasia. Furthermore, involving new participants in each focus group allowed for exploring novel insights. This approach not only increases the robustness of the study but also enhances the generalisability of the findings to a wider population of individuals living with achalasia.

Data collection

This study involved three in-depth, semi-structured focus groups facilitated by the researcher in collaboration with a supervisor. Participants in the current study were allocated to one of the three focus groups based on their availability. Focus groups were held over four months, with the first two being two weeks apart from November 2020 and the last one held in February 2021. We aimed for a maximum of eight participants in each focus group. The aim of the study, the structure of the focus groups and the topics of discussion were stated at the beginning of each online session. The ground rules were explicitly stated and included confidentiality, raising concerns during sessions and the option to withdraw from participation. The online focus groups lasted around 2 hours and were recorded for accuracy check purposes. Two female researchers facilitated each session. Facilitation of the sessions was conducted by two female researchers, with the first session facilitated by two pharmacist researchers, and subsequent sessions led by a pharmacist and a health psychologist, respectively. The researcher and supervisor actively facilitated the discussions, providing guidance and support as needed and addressing any queries or concerns raised by participants in the chat box. This collaborative facilitation approach ensured that all participants had the opportunity to contribute their insights and perspectives. Consensus-building played a pivotal role throughout the focus group sessions, ensuring that the perspectives and insights of all participants were thoroughly considered and integrated into the intervention design. At the conclusion of each session, participants were actively encouraged to share their thoughts and opinions on the discussed techniques and interventions. Consensus was sought by facilitating open dialogue and inviting participants to express their agreement or dissent with the proposed components of the intervention. The researcher and facilitators provided a supportive environment for discussion, addressing any points of uncertainty raised by participants. Consensus was confirmed when all participants at the end of each session agreed on the proposed components and co-designed intervention derived from the preceding focus group discussions. This iterative process of consensus-building ensured that the intervention reflected the collective preferences and needs of the participants.

Focus group 1

Participants in the first focus group were presented with a list of eating behaviours derived from previous research exploring people's experiences living with achalasia. (6) Participants were asked to prioritise those eating behaviours from the most to least challenging. After reaching a consensus in the first focus group, participants started discussing their ideas and opinions about the techniques that could facilitate a change in behaviour.

Focus group 2

In the second focus group, participants were asked to discuss and co-design an intervention using the COM-B model. Those BCTs, which were shown to be effective in other behavioural change studies, were presented to the participants. Participants were asked to discuss and comment on the techniques and share their experiences in order to tackle the challenges with the chosen target behaviour; this included eating in a new environment or eating with different people. The researchers provided examples and prompts, such as making a food diary or educating friends and family, to participants and asked them to discuss other similar techniques that can help them change their eating behaviour. Participants were asked to add more examples of techniques that map onto each element of the COM-B Model.

Focus group 3

In the final focus group, participants were presented with the findings from the previous focus group sessions. They were asked to confirm whether the proposed techniques would be suitable for them as well. They were also asked to discuss the delivery method of the co-designed intervention, i.e., an online platform or printed materials such as an evolving workbook that can be personalised based on individual's needs.

At the end of each focus group, the researchers recapped discussion points and ensured everyone agreed with the accuracy of the summary of information from what was shared in the online session. Participants' discussions in the online focus groups were structured using the COM-B model as the theoretical framework and formed the basis of the developed intervention.

Data analysis

The collected data from each online focus group underwent a rigorous analytical process guided by the COM-B (Capability, Opportunity, Motivation - Behaviour) model. Following each session, the research team engaged in comprehensive discussions to review and refine the main points extracted from the focus groups. These discussions were instrumental in identifying techniques and activities related to participants' perspectives on managing their eating behaviour in social settings within the context of achalasia. By discussing the collected data within the research team, the suggested techniques were systematically categorised into the respective components of the COM-B model. This categorisation facilitated a structured approach to understanding the factors influencing participants' behaviours and informed the development of targeted interventions. Repeated listening to the video recordings enabled the identification and highlighting of various techniques and interventions proposed by participants. The suggested techniques, such as ways to manage expectations (feedback and monitoring) or getting support from a buddy (social support), were in line with the elements of the COM-B model, providing a theoretical framework for interpretation.

In the final session, participants were actively engaged in validating the identified techniques and co-designing interventions based on the insights gathered from the previous focus groups. Through consensus-building discussions, participants confirmed the potential effectiveness and feasibility of the discussed components, ensuring alignment with their needs and preferences. Overall, the analytical approach employed in this study involved iterative data refinement, categorisation based on the COM-B model, and validation through participant feedback, ultimately leading to the development of a comprehensive and participant-centred intervention strategy.

Results

The results are organised according to the constructs of the COM-B model, which include Capability, Opportunity and Motivation, which are necessary conditions for the desired behaviour change. A specific behaviour needed to be highlighted and the elements of the COM-B model were required to change that behaviour. The domains of the TDF, including knowledge, skills, emotions, intentions, beliefs about capabilities and memory informed the content of each element of the COM-B model, which allowed the participants to co-design an intervention to change that specific behaviour.

Participants provided rich insights into living with achalasia for each element of the COM-B model. They identified the target behaviour, which was eating in a social setting, then discussed strategies that were implemented to facilitate behaviour change. Participants in this study agreed that the co-designed intervention to help them change the target eating behaviour would be an evolving workbook that can be tailored and personalised based on the needs of each individual living with achalasia. The workbook can include a variety of techniques that can help people with different challenges at different stages of eating in a social setting. This can include the challenges before, during and after eating in that setting, such as eating in public or eating with new people.

Sample

This study included 24 participants living with achalasia. The age range of participants who completed the questionnaire was from 29 to 77 years (mean 53, SD 14.19). All participants reported trying to change their eating behaviour in the past. Five participants reported managing their symptoms with no medical interventions. Fifteen participants had one medical procedure (HM n=10; PD n=3; Botox n=2) and four participants underwent multiple medical treatments (HM and PD n=2; HM and PD n=1; HM and POEM n=1; PD and Botox n=1). All participants reported having symptoms of achalasia even after medical treatment. Eight participants participated in the first focus group, eight in the second focus group and eight in the last focus group. Table 1 shows the demographic details of the participants.

Table 1: Participant's demographics

Participant demographics	**All participants**	**(n=24)**
Gender	Male	n=3 (12.5%)
	Female	n=21(87.5)
Age (years)	Mean (SD)	53 (14.19)
	Range	29-77
Ethnicity	White	n= 23 (96%)
	Asian	n= 1 (4%)
Living status	Living alone	n=4 (16%)
	Co-habiting	n= 20 (84%)
Employment status	Full-time	n= 8(33%)
	Part-time	n= 7 (29%)
	Retired	n=8 (33%)

	Not working n=1 (4%)
Attempted to change eating behaviours in the past.	n=24 (100%)

Behaviour

The target behaviour for this study was 'eating in a social setting' which was prioritised and chosen by participants amongst a long list of behaviours which was identified from previous research, and they included the time of meals, types of food and different settings in which they eat. Eating in a social setting was identified as the most challenging eating behaviour as it impacted participants' quality of life the most. When presented to participants, different aspects of the target behaviour were discussed, such as who is performing the behaviour, what do they need to do differently to make a change, when, where and how often they will do it and who do they get support from. In order to change a behaviour, it is important to identify the population that are performing the behaviour, the specific behaviour or behaviours that need to be changed to solve the problem and the location in which the behaviour happens. A target behaviour can be selected through gathering all potential behaviours that are related to the problem to be addressed. It is important to consider some criteria while choosing the targeted behaviours, and those include the impact if that behaviour was changed, the complexity of changing that behaviour, the potential spill over effects and the ease of measuring its effectiveness. Once the target behaviour is selected, it is then important to include a detailed description of that behaviour in order to be able to make a change. Table 2 outlines a list of techniques reported by participants that can be performed to change the target behaviour.

Table 2: Intervention type based on different components of the COM-B model

COM-B components	Techniques suggested by participants (Intervention function: Behaviour Change Technique (BCT): Example)
Physical capability	Training: Exposure: Building the stamina to tolerate new environments
Psychological capability	Education: Instruction on how to perform a behaviour: Increasing knowledge about the menu or the restaurant before eating in an unfamiliar setting
Physical opportunity	Enablement: Reduce negative emotions: Trying to reduce negative emotions when eating in an unfamiliar setting through stress management skills.
Social opportunity	Modelling: Practical social support: Using techniques used by other people to increase confidence when eating in an unfamiliar setting
Reflective motivation	Incentivisation: Self-reward: Set a reward after enjoying and embracing eating in an unfamiliar setting.
Automatic motivation	Persuasion: Instruction on how to perform a behaviour: Speaking to others living with achalasia to induce positive feeling about eating in an unfamiliar setting.

Capability

Capability can be described as the individual's psychological and physical capacity to engage in the activity. (15) Both physical and psychological capability can be improved through interventions. It is crucial to understand why and how to make the change along with having the capacity and skills to sustain it. Participants were presented with a few of the techniques within the capability element and were asked to discuss potential activities that could be incorporated in the intervention. The two techniques that were presented to the participants were feedback and monitoring; and shaping knowledge as these were the techniques shown to be effective in other studies for changing behaviours. (15) When participants were presented with the capability component, they discussed how physical and mental ability to change eating behaviour in public is important. This includes the need of knowledge, such as familiarising themselves with the menu and the stamina to tolerate the new environment to perform a behaviour change. The quotes below demonstrate examples of the behaviour change techniques discussed by participants in the focus groups.

Feedback and monitoring

The following quote provides instruction on how to perform a behaviour and provides feedback on performance on the target behaviour:

'My view on this is before you go to a restaurant, to be in a mindset, because you want to enjoy your meal, you don't want to be anxious; you have to live with your condition. So, I feel that you have to compose yourself, meditate, breathe deeply, possibly have a little bit to eat beforehand so that you are not incredibly hungry, so you don't go to the restaurant with low sugar levels, being anxious, being worried because you're there to enjoy your company.' (participant 1,focus group 2,female)

Shaping knowledge

One participant talked about the lack of knowledge of others and how that can lead to stress when eating in public:

'It all boils down to the understanding of knowing what achalasia is, because if you said you were celiac, people now know that you don't have gluten. People know about that now. So, when you say achalasia depending on who you're with, you know they don't have a clue what you're talking about.' (participant 1, focus group 1, female)

A few participants explained how having a card to explain what achalasia is in simple language could help explain the condition to other people.

‘I think having that ‘card’ is very useful as just a bit of a script and I think even though you might have that ‘card’ it is going to be once you start getting used to it that it’s going to be a very useful tool to have.’ (participant 2, focus group 2, male)

Another participant mentioned how looking at the menu prior to eating out can give them the knowledge of what they can eat when they are in an unfamiliar social setting.

'I have to admit my first thing when I look at a menu and as others have said as well, I will if it's online beforehand I will always do that as well and I tend to go through menus not with what I

would like to eat, but I look at all the sort of options and think well, can't have that! Can't have that! Can't have that! and then I'll look and think oh, out of the three things out of 20, which one could I possibly have?' (participant 3, focus group 2, female)

Opportunity

Opportunity can be described as all the factors that lie outside the individual that make the behaviour possible. (15) This can include having the time and the financial resources to make the habit. These are factors in the environment that encourage or discourage achieving behaviour change. The two techniques that were presented to the participants in this study were antecedents and regulation as they were shown to be effective in other research. (16) These include restructuring the physical/social environment (antecedents) and reducing negative emotions (regulation). Participants discussed both physical and social aspects of this element. This included finding ways to overcome barriers such as reducing stress or changing the environment and creating a more suitable space to perform the desired behaviour.

Restructuring the physical/social environment

One participant mentioned how restructuring the environment would put her mind at ease and she could go back to her eating after calming herself down.

'Now I abandoned the meal completely. If I'm feeling hot and flustered, I'll go and sit in a cool place, sometimes I have to take up the meal with me, if that's not going to work, the meals put aside, I sit down, collect my thoughts, and perhaps an hour later I'll have my meal.' (participant 1, focus group 3, female)

Reducing negative emotions

A participant mentioned how negative emotions such as stress could cause problems while eating out.

'I've just thinking one thing when we were talking about negative emotions, never eat when you're really stressed, or if you've had a major disagreement with someone, it will bounce back on you, literally. You've got to wait to calm down. Researcher asks: is there anything you do to calm yourself down? *Deep breathing, fresh air, cool, literally cool myself physically, to calm down before I eat.' (participant 2, focus group 3, female)*

Another participant mentioned the effects of relaxation techniques and altering postural structure in order to help with eating.

‘I’ve always done Pilates throughout my life and I find this a saving grace as well. The continual stretching and posture and remembering the relaxation of the sitting and techniques that we we’ve got to adopt. No hunching when you’re eating and sitting, breathing, relaxing.’ (participant 1, focus group 3, female)

Motivation

Motivation is described as ‘all the brain processes that energise and direct behaviour’, not just goals and conscious decision-making. (15). The techniques within the motivation element include goals and planning and social support. These were the techniques that were presented to the participants in this study as they were shown to be effective in other research. (15) The reflective and automatic motivation were discussed by the participants. Developing a plan to promote the desired behaviour and the social support were key points that were discussed in the focus groups.

Goals and planning

One participant mentioned how having a plan will help her eating in a social setting.

‘I just always have a plan of action when I get to the restaurant, and I always talk to the staff there about what the food actually is, I’ll make sure that it it might say something on the menu and then I find well, after seeing someone else with it, I think that’s very dry, and it doesn’t seem to be any sort of gravy. So, I mention all these sorts of things, like vegetables can be whole, but they gotta be mashable that that sort of texture and need a sauce of some sort. I just talk to them and that’s that seems to help.’ (participant 2,focus group 1, female)

Social support

A participant described how an online support group has been helpful since she got her diagnosis.

'So I've really had no support from the hospital and from the consultants at all, and everything I know and everything I've done is being based on advice from people and I completely agree with you I see some people saying that they can eat something, and I couldn't go near it and then other people suggesting something else that works for me. So, I think the online support has been good because you're getting a really broad range of very different people and you can pick and choose the advice that works for you.' (participant 3,focus group 1, female)

Delivery method

In the final session, participants unanimously approved the techniques proposed in previous sessions, without introducing new elements. They deliberated on delivery methods for the co-designed intervention, specifically focusing on tools to aid in social eating situations. Given their access to an information pack via the support group, participants suggested an evolving workbook tailored for social settings. They emphasised the importance of editability for personalisation based on individual needs. They discussed having an evolving workbook that has different sections to use and adapt as needed. A workbook was suggested to the participants by the research team in the last focus group, which can include different sections and can have the flexibility of having a hard copy and a printable online version. Participants agreed on having a workbook to address this particular/specific issue which can work well alongside the [broader or more general] information available to them through the Achalasia Action support group. After discussing this with the research team and the administrators of the Achalasia Action, the co-designed intervention could be embedded online on the official Achalasia Action website that could be accessed by members of the Achalasia Action as well as the public.

Overview of findings

Participants in this study agreed that an evolving workbook which includes different sections based on the COM-B model, would be the most suitable intervention for people living with achalasia to facilitate eating in a social setting. Goals and planning, feedback and monitoring, antecedents, shaping knowledge and social support were the techniques highlighted in the focus groups to be included in the workbook to help people living with achalasia change their eating behaviour in a social setting. They also confirmed that the intervention should be a workbook available in hard copy and online.

Discussion

This is the first study to the authors' knowledge that used the COM-B model to co-design an intervention to help people living with achalasia change their most challenging eating behaviour. In this study, participants prioritised eating in a social setting as the most challenging eating behaviour, and the COM-B model was used to co-design the behaviour change intervention. The innovative approach taken in this study lies in its utilisation of the COM-B model for co-designing an intervention aimed at addressing the most challenging eating behaviour among individuals living with achalasia. By focusing on the specific issue of eating in a social setting, this study fills a crucial gap in existing research, as it is the first known instance of employing the COM-B model for this purpose within the context of achalasia.

Moreover, the study's emphasis on co-designing the intervention with the involvement of participants adds another layer of originality. This participatory approach not only ensures that the intervention is tailored to the specific needs and challenges faced by individuals living with achalasia but also enhances the likelihood of its effectiveness by incorporating the insights and perspectives of those directly affected by the condition. By combining a novel theoretical framework, the COM-B model, with a participatory approach to intervention design, this study breaks new ground in the field of achalasia research and offers valuable insights into addressing the unique eating challenges faced by individuals living with this condition.

Capability

This research highlighted that a lack of information can lead to stress and trigger symptoms when eating in a social setting. Similarly, a lack of information has also been shown to impact capability in relation to making lifestyle changes and adhere to treatment when diagnosed with gestational diabetes mellitus (GDM). (17) Women with GDM needed to be provided with adequate health information, appropriate educational resources and patient-centred counselling to achieve lifestyle changes. (17) A lack of information and monitoring in people living with achalasia results in stress and anxiety, which affects eating behaviour. All participants in this study discussed the importance of preparing themselves before eating out, including increasing their knowledge by reading the menu in advance or creating an informative tool to explain their situation to others. The results of this study also show that feedback and monitoring on past events and gaining information can reduce stress when it comes to eating in a public setting, hence reducing the challenges with eating.

Opportunity

Our findings show that people living with achalasia can reduce their negative emotions by engaging in activities, such as reading the menu before eating in a social setting, and restructuring their physical and social environment, such as taking a break from the dining table. This finding aligns with the study carried out by Carney et al., where researchers used the COM-B model to develop an intervention to promote physical health for young people. (15) Environmental factors were shown to be crucial when developing the intervention (18) and a local gym with a safe environment was encouraged rather than exercising outdoor. These finding highlight the importance of the social and physical environment in facilitating behaviour change.

Motivation

The current study demonstrate that motivation techniques, such as goals and planning and social support, help people living with achalasia reduce the challenges of eating in a social setting. Existing research suggests that social support may, directly and indirectly, improve self-care behaviours and highlights the importance of interventions that augment patients' confidence. (19) The intervention co-design in this study allows people living with achalasia to access relevant and appropriate resources through the evolving workbook, and increase confidence when eating in a social setting. It will also allow people to plan ahead and reflect on their goals when eating in a social setting.

Strength and limitations

Our study has several strengths to discuss. A qualitative approach, i.e., focus groups, allowed the researcher to obtain insights into people's experiences living with achalasia and their insights for co-designing an intervention to change a particular eating behaviour. People were recruited through Achalasia Action, a platform where people share their experiences; therefore, when co-designing the intervention, they could share what interventions had worked for the majority and what had not. The COM-B model provided a theoretical framework that the researchersrs used to develop and co-design an appropriate eating behaviour change intervention for eating in a social setting. The different elements of the COM-B model, i.e., capability, opportunity and motivation, the TDF and its techniques, along with patient and public involvement facilitated the intervention co-design.

We acknowledge some limitations of this study. In relation to our recruitment, the participants in this study were recruited from the Achalasia Action support group. This may have introduced a bias and impacted the generalisability of the findings to the wider achalasia patient population. However, upon discussion with several clinicians, and considering the rarity of the disease, it was decided that this was the most suitable recruitment approach to ensure the study was feasible.   As the sample consisted of people living with achalasia who were part of Achalasia Action, they had received support through the online platform and regular meetings. People who are part of the support group have benefited from meeting other people and getting help and support from people who have a diagnosis of achalasia for many years therefore they are somewhat more prepared to cope with the challenges of the condition. People living with achalasia who are not part of the Achalasia Action and have not tried any interventions in the past may have a different perspective when it comes to co-designing an intervention. The study aimed to co-design an intervention to change eating behaviour for people living with the condition; therefore, our sample is representative for the purpose of this study.. Despite these limitations, our findings are consistent with the evidence in the literature, which were conducted in different populations and may be applicable to people living with achalasia and also those who are not part of the support group and do not live in the UK.

Future research

Future studies should explore the feasibility of the co-designed intervention, which is an evolving workbook including different sections such as reflection, activities and goal setting. If feasible, the co-designed intervention can be piloted to all the members of the support group.

Conclusion

Using a focus group approach with COM-B model and TDF as the theoretical framework, an intervention to support people living with achalasia with eating in a social setting was developed and the specific content of the components in the intervention were identified. The target behaviour identified was eating in a social setting. The focus groups identified an evolving workbook as the appropriate intervention to help people prepare for different challenges arising from eating in a social setting. The results also emphasised the importance of different elements of the COM-B model and the techniques. Considering the challenges with eating in a social setting, social support, activities to reduce stress, preparation and planning ahead, and increasing awareness are necessary to overcome the barriers. In order to achieve long-term sustained behaviour change, engagement with a personalised workbook could address the challenges of eating in a social setting.

Declarations

Ethics approval and consent to participate

A favourable opinion for conduct was given by the University of Reading School of Chemistry, Food and Pharmacy Research Ethics Committee (SREC 40/2020). All methods were carried out in accordance with the approval and informed consent was obtained from all participants.

Consent for publication

Not applicable.

Availability of data and materials

The datasets generated and/or analysed during the current study are not publicly available because participants can be identified from them but the anonymised data are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

MK, AH, RL and MH made a substantial contribution to the design of the work. MK conducted the focus groups along with AH and RL. MK, AH, and RL extensively discussed how to analyse and interpret the data. AH and RL contributed to and supervised the analysis of the collected data from the focus groups. MK, AH and RL discussed the content and the layout of the co-designed workbook. All authors (MK, AH, RL and MH) revised the manuscript critically for intellectual content, agreed and approved the final version to be published.

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List of abbreviations

LOS: Lower Oesophageal Sphincter

GORD: Gastro-Oesophageal Reflux Disease

BCW: Behaviour Change Wheel

COM-B model: Capability Opportunity Motivation - Behaviour model

TDF: Theoretical Domains Framework

BCT: Behaviour Change Techniques

UK: United Kingdom

GDM: Gestational Diabetes Mellitus

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Chapter 5

5. A co-designed intervention to support people living with achalasia to eat in a social setting: a feasibility study

Chapter 5 presents the publication:

Kalantari M, Hollywood A, Lim R, Hashemi M. Co-designed intervention to enable people living with achalasia to enjoy eating in a social setting: a feasibility study (in preparation to be submitted to BMC Pilot and Feasibility studies).

5.1 Introduction

Building on the findings from the previous research outlined in chapters 3 and 4, chapter 5 marks a vital step towards realising the potential of a patient-centred approach in supporting people living with achalasia. This chapter translates the theoretical insights and collaborative design processes of earlier work into practical action. Chapter 3 explored the multifaceted nature of achalasia, emphasising the patient-centric experience of the disorder. In response, chapter 4 utilised a collaborative approach to identify a target behaviour and co-design an intervention addressing the particular challenge. Chapter 5 now progresses to a pivotal phase: the implementation and feasibility assessment of this co-designed intervention.

Concentrating on evaluating the practicality, acceptability, and potential efficacy of the tailored workbook intervention, this chapter adopts a mixed-method approach. It not only assesses the utility of the co-designed workbook but also examines its potential effectiveness for people living with achalasia. The findings from this feasibility study offer valuable insights into how the workbook functions in a real-world setting and the degree to which it resonates with and supports people living with achalasia. This study illustrates the observed efficacies and identifies areas for optimisation, setting the groundwork for subsequent large-scale assessments.

Chapter 5 represents the integration of rigorous academic inquiry and its practical implementation. The chapter implements the collaboratively designed intervention, showing clear evidence of its effectiveness in addressing social eating issues for people living with achalasia. This chapter further highlights the cumulative nature of research, where each stage is informed by the preceding one, yielding a methodical and impactful research progression.

By taking a patient-centred co-design approach from concept to feasibility, chapter 5 adds a significant layer to the evolving narrative of achalasia care. It represents not only a step forward in the specific context of achalasia but also a broader contribution to the field of health research, showcasing the power of collaborative, participatory methodologies. Future steps, possibly including a full-scale randomised controlled trial, will further contribute to this innovative pathway towards more empathetic, effective, and personalised care for people living with achalasia.

Title page

Title

A co-designed intervention to support people living with achalasia to eat in a social setting: a feasibility study

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Abstract:

Background: Achalasia is a rare oesophageal condition that can affect eating behaviours. This study aimed to evaluate the feasibility of recruitment and assess the acceptability of a co-designed, workbook-based intervention targeting one of the most challenging eating behaviours identified by participants in previous research , which was eating in a social setting.

Methods: A mixed-method approach was employed, which involved pre and post-intervention questionnaires and semi-structured interviews. The Achalasia Action Group, a UK-based support group, facilitated participant recruitment. The intervention was a workbook designed collaboratively by the researchers and people living with achalasia, with strategies built on the COM-B model (Capability, Opportunity, Motivation). Outcome measures were based on recruitment and retention rates, the APEASE criteria for usability and effectiveness, self-reported changes in eating behaviours, and qualitative feedback from participant interviews.

Results: The study aimed to recruit 20 participants, and this target was achieved, resulting in a 100% recruitment rate. However, the post-intervention questionnaires were completed by only 10 participants, indicating a 50% retention rate from baseline. Quantitative measures demonstrated an improvement in confidence and enjoyment levels while eating in a social setting post-intervention and a decrease in symptoms such as pain, regurgitation, stress and anxiety. Qualitative feedback on the intervention described enhanced social support and improved symptom management of achalasia in a social setting. Furthermore, the intervention met the APEASE criteria, indicating its usability and acceptability.

Conclusion: The recruitment success of this study underscores the feasibility of involving people living with achalasia in intervention research. However, with a retention rate of only 50% at follow-up, it is evident that future studies should consider recruiting a larger baseline sample to ensure the target is achieved. The positive outcomes of the co-designed intervention underscore the importance of user involvement in developing interventions. The intervention demonstrated the potential to support people living with achalasia in eating in a social setting. The co-designed intervention has significant practical implications by providing healthcare professionals and support groups with a feasible, effective method to enhance the social eating experience of people living with achalasia, potentially improving their overall quality of life.

Keywords:

Achalasia, feasibility study, co-design, APEASE, intervention, behaviour change, eating behaviour, chronic condition, rare condition

A co-designed intervention to support people living with achalasia to eat in a social setting: a feasibility study

Introduction

Achalasia is defined as an uncommon, chronic condition that affects the motility of the oesophageal body along with altered lower oesophageal sphincter (LOS) relaxation. (1) Even the most effective treatments are unlikely to be curative. A multidisciplinary team, including gastroenterologist, surgeon, radiologist and dietician, are needed to obtain optimal outcomes for managing this rare chronic condition. The main goal of medical treatments and interventions are mitigation of symptoms. The medical interventions are pharmacologic, endoscopic and surgical treatments to achieve symptom relief. (2) As all medical treatments only help to alleviate symptoms, it is important for people living with achalasia to use non-pharmacological interventions to manage their condition.

In recent years, research has yielded promising findings on the effectiveness of self-help protocols delivered by audio/videotapes, brochures and manuals in addressing mental health and substance use problems. (3) While these findings are not specific to achalasia, they suggest the potential of similar self-help approaches in the management of long-term health conditions. The evidence in the current literature also shows the benefits of non-medical intervention on different chronic conditions. For example, a study carried out by Pujol et al. discussed the importance of non-pharmacological intervention, such as physiotherapy in adjunction with medical treatments for patients with cancer pain. The study also stressed the significance of attending to psychological issues such as affective distress, coping, and beliefs about cancer as a crucial aspect of pain treatment programs. Furthermore, psychophysiological interventions such as biofeedback and relaxation were employed as behavioural strategies in order to evaluate and prevent pain, and treat patients for pain or psychological distress. These interventions have been found to reduce chronic pain in cancer patients and enhance patients' quality of life. (4) Similarly, Ambrose et al. highlighted the importance of non-pharmacological interventions in treating chronic pain. These interventions can provide an alternative or complementary approach to traditional pharmacological treatments. Given the modest relief and high discontinuation rates associated with pharmacological treatments due to adverse effects, these non-pharmacological interventions are invaluable. (5) One of the examples is cognitive behavioural therapy which uses behaviour change strategies to reduce pain and fatigue. Other non-pharmacological interventions such as acupuncture, mindfulness meditation, yoga and relaxation have also become accepted forms of symptom management, with clinical trials demonstrating efficacy for pain and physical function. (5)

Based on a study carried out by Kalantari et al. (2021) exploring the experiences of people living with achalasia, self-management was a common approach people used to manage their long-term condition. (6) While a range of medical treatment options exist for people living with achalasia, these alone are often insufficient to manage the condition. Therefore, people living with achalasia often have to adopt additional techniques to alleviate symptoms or cope with new symptoms that may arise as a result of the medical treatments themselves. This emphasises the important role that people living with achalasia play in managing their long-term condition, particularly in terms of modifying daily activities, such as eating, to alleviate symptoms. Research has indicated that stress can alter eating patterns, affecting the types, quantities, and variety of food consumed. (7) Stress not only influences an individual's health behaviours but also their reactions to stressors, such as changes in eating habits. Such deviations, especially when faced with chronic stress and the challenges of managing long-term conditions, may heighten the risk of developing disordered eating behaviours. (8)

Eating disorder symptoms are linked to major problems with mental and physical health, can last for a long time, and can lead to clinical eating disorders, which are linked to substantial incidents of illness and death. (9) Therefore, prompt intervention significantly improves the exacerbation of symptoms. Self-help interventions have been suggested as the primary course of action for addressing mild to moderate symptoms of eating disorders. (10) Self-help interventions are structured programmes that people can work through on their own or with little help. They include tasks and activities based on evidence and theory. (11) These kinds of interventions are scalable, can give users privacy, easy access, and a lot of freedom, and are suggested for mild to moderate eating disorder symptoms. (12, 13)

There are interventions that promote supported self-management and can improve long-term outcomes by providing individuals with skills and information for them to manage chronic conditions effectively. (14) It is debated whether interventions to change behaviour should have a strong theoretical background to promote change. However, interventions based on behaviour change theory in certain long-term conditions, such as rheumatoid arthritis and lower back pain, have shown the potential to improve long-term behaviour. (15) In a comprehensive meta-analysis and systematic review conducted by Cradock et al., which focused on dietary behaviour modification techniques implemented in Type 2 Diabetes management, a subset of four distinct BCTs were pinpointed as efficacious in reductions in HbA1c (a marker of long-term blood sugar control). These encapsulated techniques of problem-solving, provision of feedback on behaviour, integration of objects into the environment, social comparison, and application of relevant theoretical frameworks. (16)

Research highlights the importance of supporting self-management of long-term conditions and this can be achieved through interventions based on theory and evidence. Kalantari et al. (2021) conducted an in-depth examination of the journey experienced by people living with achalasia, elucidating the sequential steps involved and identifying areas necessitating additional support. (6) Based on the data collected in the initial study and the insights gained from it, eating behaviour was the main concern raised therefore a subsequent study was conducted to address this. Kalantari et al. (2023) employed a co-design approach to identify a specific eating behaviour and develop an intervention in collaboration with people living with achalasia. The specific challenge that was identified was eating in a social setting, which is a primary concern faced daily by people living with achalasia. (17) Informed by the collaboration between researchers and people living with achalasia, as well as grounded in scientific evidence and the Theoretical Domains Framework (TDF), the content of the intervention was co-designed. A self-directed workbook was confirmed as the appropriate mode of delivery and it was iteratively developed by participants and researchers. The theory-based workbook comprises three chapters, co-designed by the researchers and people living with achalasia. It starts with instructions on how to use the workbook. The content of the workbook is developed using the Behaviour Change Wheel (BCW), which applies the COM-B model (Capability, Opportunity, and Motivation-Behaviour) and the Theoretical Domains Framework (TDF). Each chapter starts with quotes from other people living with achalasia, sourced from the co-design study carried out by Kalantari et al. (17) The chapters then introduce various activities and techniques to address the specific behaviour of eating in a social setting.

Informed by these previous studies, the aim of the current study was to explore the feasibility of recruitment and the effectiveness of the intervention in promoting positive changes in eating behaviours in social settings. The purpose of feasibility studies is to determine whether further testing of an intervention is necessary; they allow researchers to determine whether or not the ideas and findings can be made relevant and sustainable. Such research may identify what needs to be modified in the research methods or protocols and how such modifications may be implemented. (18) By evaluating its efficacy, we sought to investigate the extent to which the co-designed intervention could facilitate desired behavioural changes in people living with achalasia. This study also explored the practical aspects of recruitment and evaluating the feasibility of enrolling participants for the intervention evaluation. By examining both the feasibility of recruitment and potential effectiveness, we aimed to provide valuable insights into the viability and potential impact of implementing the co-designed intervention within real-world settings.

Aim and objectives

This study's primary aim is to assess the feasibility of undertaking a study evaluating a novel co-designed intervention for people living with achalasia to enjoy eating in a social setting. Key study objectives were informed by existing feasibility guidelines (9, 18) and are to: (1) explore the feasibility of recruiting and retaining participants in the study, (2) determine the acceptability of measures and research procedures, and (3) conduct a mixed methods process evaluation to determine the acceptability of the intervention to participants. A secondary aim is to explore the potential efficacy of the intervention in changing the behaviour of people living with achalasia and to use this to inform the required sample size for an intervention of a larger, future trial.

This study distinguishes itself from its predecessors through a pivotal shift from understanding to action, translating theoretical insights into practical interventions for individuals living with achalasia. While the previous two studies provided foundational insights into the multifaceted experiences of those living with achalasia and co-designed an intervention targeting a primary concern, the third study aims to represent a crucial progression towards implementing and evaluating the feasibility of the co-designed intervention in a real-world setting. Moreover, it demonstrates the cumulative nature of research, building upon the insights and findings from preceding studies to establish a methodical and impactful progression in understanding and addressing the challenges faced by individuals living with achalasia. Through its patient-centred co-design approach, this study not only contributes to the evolving narrative of achalasia care but also sets a precedent for more empathetic, effective, and personalised care approaches in the broader field of health research.

Methods

Design

The study employed a mixed-methods approach, utilising both pre-post intervention questionnaires and semi-structured interviews. The questionnaires were used to quantitatively assess changes in eating behaviours and achalasia symptoms along with gathering feedback on the usability and design of the workbook. In developing the questionnaires, the researcher conducted a thorough review of existing literature and regularly met with supervisors to create the questionnaires, aligning them with the study's objectives. While the questionnaires underwent rigorous design processes, including careful consideration of questions wording, response options, and overall structure, it is important to note that formal validation procedures were not conducted. The decision to not conduct a formal validation procedure for the questionnaires was primarily influenced by several factors. Firstly, the study focused on evaluating the feasibility and initial effectiveness of the co-designed intervention rather than developing a new measurement instrument. Additionally, time and resource constraints limited the ability to conduct comprehensive validation studies within the scope of this research.

Semi-structured interviews provided qualitative insights into the participants' experiences and perspectives, further aiding in the evaluation of the feasibility and potential effectiveness of the co-designed intervention. A favourable ethical opinion was granted through the University of Reading School of Chemistry, Food and Pharmacy Research Ethics Committee (SREC 51/2022).

Sample size

In determining the sample size for this study, several factors influenced the decision to include 20 participants. Firstly, given the exploratory nature of our research, a smaller cohort was deemed appropriate, allowing for an in-depth examination of individual experiences and perspectives. This smaller sample size facilitates a more nuanced understanding of the complex issues surrounding achalasia, ensuring that each participant's insights can be thoroughly explored and analysed. The specific criteria and rarity of achalasia further limited the pool of potential participants. Additionally, constraints related to time and resources were a factor. Taking all these considerations into account, a sample size of 20 was determined to be both suitable and manageable for the study's objectives.

Procedure

The study involved assessing the feasibility and potential efficacy of the behaviour change intervention. Baseline measures included a quantitative pre-intervention questionnaire that collected data on participants' demographics and eating behaviour. Participants were asked to complete the pre-intervention questionnaire before they attempted to use the workbook. Following that, the intervention was implemented, during which participants were introduced to the workbook and had the opportunity to put its contents into practice. After completing the workbook, participants completed a post-intervention questionnaire, which assessed current eating behaviour and beliefs, along with the design and usability of the workbook. Subsequently, an online one-to-one interview was conducted to gather in-depth feedback and personal insights regarding participants' experiences with the workbook and the intervention as a whole.

In this study, we initiated the process with an online pre-intervention questionnaire completed by the participants. This initial step aimed to capture baseline data concerning the participants' beliefs and behaviours regarding past eating behaviours in social settings. Following the questionnaire, participants were introduced to the co-designed workbook, which they engaged with independently and at their own pace. This self-guided stage allowed them to absorb and apply the intervention in a timeframe and manner most comfortable for them. Upon completion of the workbook, participants were asked to complete a post-intervention questionnaire. This was a critical stage in the study, intended to assess any changes in participants' perceptions and behaviours resulting from the intervention. Within this post-intervention questionnaire, an option was provided for participants to express their interest in taking part in a one-to-one interview. Those who showed interest were subsequently scheduled for an online one-to-one interview, this provided a qualitative perspective and rich, in-depth insights into their experiences with the workbook, including aspects of design, content, and usability.

The APEASE criteria can be used by intervention designers to identify the intervention functions, policy categories, behaviour change strategies, and delivery methods that are most suitable for their context and, therefore, most likely to be implemented and have an impact. APEASE is Affordability, Practicality, Effectiveness and cost-effectiveness, Acceptability, Side-effects/safety, and Equity of the intervention. (19) In this study, we employed APEASE criteria to structure the interviews, thereby obtaining deeper insights into the potential impact of the intervention.

Recruitment

Recruitment was facilitated by Achalasia Action, which is an independent charity supporting people living with achalasia in the United Kingdom (UK). The researcher emailed the study recruitment letter and information sheet to the administrator of Achalasia Action, who then sent these on to their members using a mailing list. (20)

The inclusion criteria for this study were as follows: anyone who lives in the United Kingdom, aged 18 years or over, has a confirmed diagnosis of achalasia (self-reported), can complete or attempt to complete the co-designed workbook, had not taken part in the previous co-design study which developed the intervention under evaluation, can access the internet for communication via Microsoft Teams and can read, speak and understand English. Participants were informed in the participant information sheet that if they had participated in the previous co-design study, they were ineligible to participate in this study.

Participants who registered their interest to take part in this study received the participation information sheet and a link to the online consent form by email, which was hosted on JISC Online Surveys. (21) The information sheet explained the voluntary nature of the study and the potential risks and benefits. The recruitment stopped when the target number of participants (20 participants) completed the baseline measures.

Data collection

Participants were sent the pre-intervention questionnaire in November 2022, and they were given up to two months to complete the questionnaire and attempt to use the workbook. They were then asked to complete the post-intervention questionnaire in January 2023 and participate in an interview in February 2023. After completing the consent form, participants were sent a link by email to complete the online demographic questionnaire along with the pre-intervention questionnaire, also hosted on JISC Online Surveys. Once the demographic details and the pre-intervention questionnaire were completed, participants were emailed a printable version of the intervention, i.e., the workbook. Participants were asked to print the workbook or contact the researcher to receive a printed copy by post. Participants were given up to two months to complete the workbook. Participants indicated they had finished the workbook by emailing the researcher and were then sent a link to the post-intervention questionnaire. Participants who completed the post-intervention questionnaire were asked to indicate whether they were interested in taking part in a 30-minute one-to-one online semi-structured interview using Microsoft Teams (an online meeting platform).

Pre-intervention questionnaire

The pre-intervention questionnaire included questions on the demographic details of the participants in order to describe the sample in the current study. It also asked participants questions about the number of times in which they ate in a social setting in a set period of time, the level of enjoyment and confidence when eating in a social setting, and the symptoms experienced when eating in a social setting. Participants were asked to grade their symptoms of pain, heartburn, and regurgitation on a scale from 1 to 5, with 1 experiencing no symptoms and 5 having severe symptoms. This self-report scale provided a standardised measure of symptom intensity for each individual. The aim of these questions was to explore the impact of using the intervention workbook.

The intervention workbook

The theory-based intervention comprised a workbook with three sections, co-designed by the researchers and people living with achalasia. The workbook, presented in the English language, comprised 29 pages and was formatted in A5 size. The content of the intervention was developed using the Behaviour Change Wheel (BCW), which applies the COM-B model (Capability, Opportunity, and Motivation-Behaviour) and the Theoretical Domains Framework (TDF). Each chapter started with quotes from other people living with achalasia, sourced from the co-design study carried out by Kalantari et al.(2023). (17) These quotes provided real-life perspectives on the experiences and challenges faced by those with the condition, particularly focusing on the primary target behaviour: eating in a social setting. For instance, one quote stated, "I accept my condition and try to eat what I can eat confidently." The aim of the quotes was to give ideas to people using the workbook to explore and try different options and activities in order to help them enjoy eating in a social setting. The sections then introduced various activities and techniques to focus on the target behaviour. For instance, the workbook guided participants through goal-setting for comfortable eating in public, planning and implementing changes in their approach, and strategies to reduce negative emotions associated with eating socially. These components collectively aimed to equip individuals with tools and coping strategies to improve their comfort and confidence in social setting situations.

Participants were given instructions on how to use the workbook. They were provided additional spaces to add any further comments or feedback on the content and design of the workbook in order to discuss with the researcher in the one-to-one interview.

Post-intervention questionnaire

The post-intervention questionnaire included repeated eating behaviour measures, i.e. similar questions to the pre-intervention questionnaire, as the aim of the questionnaires was to compare the data before and after using the workbook. The questionnaire also included a series of feedback questions on the content of the workbook, its usability and practicality. Participants were then asked whether they wanted to take part in an interview to share further feedback on the workbook.

Online interviews

Upon completion of the post-intervention questionnaire, participants were invited to take part in an online interview to share their personal experiences and thoughts related to the workbook. Conducted via Microsoft Teams, these interviews followed a semi-structured format, which allowed for flexibility in discussion and ensured core topics were addressed. The interview protocol was designed to explore participant perspectives on the content, design, and usability of the workbook, as well as the perceived effectiveness of the intervention. The interviews also provided a platform for participants to voice any potential challenges or barriers they encountered while engaging with the intervention. The detailed qualitative insights derived from these interviews were crucial in further assessing the feasibility and potential impact of the intervention in a real-world context.

Data analysis

The quantitative data gathered from pre- and post-intervention questionnaires were subjected to descriptive statistical analysis. This provided a summary of the central tendency, dispersion, and distribution patterns of the participants’ responses.

The feasibility of the workbook was assessed to determine its practicality and usability. Quantitative data gathered from the questionnaires provided valuable insights into changes in eating behaviours, achalasia symptoms, and feedback on the workbook's usability and design.

The changes in participants' behaviours and related symptoms were quantified using a Likert scale ranging from 1 (not at all severe) to 5 (very severe), to measure the potential effectiveness of the intervention. While formal testing of significance was not feasible due to sample size limitations and it was not the primary aim of the study, observing meaningful changes provides valuable insights into the intervention's clinical relevance and preliminary effectiveness. Additionally, participant feedback on the intervention's acceptability and feasibility was gathered through Likert scale responses, aiding in iterative improvements and informing future research directions.

In parallel, for the qualitative data drawn from the post-intervention interviews, the APEASE criteria was utilised (Acceptability, Practicability, Effectiveness, Affordability, Safety, and Equity) as a guiding framework. This approach helped us systematically categorise participants' feedback and experiences, giving us rich, contextualised insights into their perception of the intervention's utility, design, delivery, and content. Taken together, this combined approach offered us a holistic understanding of the intervention's impact and its potential for further implementation. The acceptability of the intervention was assessed through qualitative interviews, which elicited participants' feedback on their experiences and perceptions. Practicability was evaluated by considering the feasibility and practicality of implementing the intervention in real-world settings. Effectiveness was examined by assessing changes in eating behaviours and related symptoms reported by participants. Affordability was not specifically analysed in this study, as the intervention is intended to be available free of charge to participants of the support group, however, participants were asked whether they would be happy to print the workbook for future use and whether the cost of printing could be an issue for them. Safety was monitored throughout the intervention period, ensuring that no adverse effects or risks were encountered. Finally, while the study sample may have lacked diversity, equity was taken into account by considering the intervention's potential applicability and benefits for people living with achalasia across diverse backgrounds. This evaluation method allowed for a more in-depth understanding of the user's reaction to the intervention's design, delivery, content, and influences on understanding and engagement. In conjunction with the APEASE criteria and descriptive statistical analysis, the Capability, Opportunity, and Motivation-Behaviour (COM-B) model was used as a theoretical framework to guide the interpretation of the data. This model supported the deductive analysis of key factors influencing participants' changes in behaviour as a result of the intervention. In the context of the study, 'capability' refers to participants' ability to implement the strategies proposed in the workbook, 'opportunity' refers to the external conditions facilitating or hindering their engagement with the intervention, and 'motivation' refers to the intrinsic and extrinsic processes that energise and direct their behaviour.

Result

Sample

Twenty people provided informed consent and completed the pre-intervention questionnaire. One participant completed the consent form but did not complete the pre-intervention questionnaire; therefore was omitted from the study. Ten participants completed the post-intervention questionnaire, yielding a 50% response rate, and five participants took part in the interview. The 20 participants who completed the pre-intervention questionnaire received the co-designed intervention by post (n=6) or email (n=14). Interviews with the five participants lasted between 17 and 28 minutes (mean=23.2 min).

A total of 20 participants were recruited for the study. Ten participants were retained for both baseline and follow-up assessments, comprising the completer group, while the remaining ten were categorised as non-completers, having solely completed baseline measures. This comparison aims to shed light on factors influencing study participation and engagement, although it is essential to note that the analysis remains descriptive in nature, lacking statistical inference.

Table 1 displays the demographic characteristics of participants across both groups. While both cohorts exhibited a diverse age distribution, a significant majority were aged over 54, with no substantial deviation between completers and non-completers. Female participants constituted the majority 85% (n=17) across both groups, indicating a consistent gender distribution. Among the 20 participants recruited for the study, various employment statuses were observed. Retirement emerged as the predominant category, with 45% (n=9). Full-time employment constituted a significant subset of individuals, with 25% (n=5) of participants dedicated to full-time work. Solely one participant 5% (n=1) reported being unemployed, and a small percentage 5% (n=1) of participants were classified under the "other" category.

Table 1. Demographic data of participants (n=20)

Variable	**Non-Completers**	**Completers**	**Total**
	Demographics		
Number of participants	**10**	**10**	**20**
Age (years)			
18-24	1 (10%)	0	n = 1 (5%)
25-34	0	1(10%)	n = 1 (5%)
35-44	2 (20%)	2 (20%)	n= 4 (20%)
45-54	3 (30%)	2(20%)	n= 5 (25%)
Above 54	4 (40%)	5 (50%)	n= 9 (45%)
Gender			
Male	2 (20%)	1 (10%)	n= 3 (15%)
Female	8 (80%)	9 (90%)	n= 17 (85%)
Employment status			
Full-time	3 (30%)	2 (20%)	n=5 (25%)
Part-time	3 (30%)	1 (10%)	n= 4 (20%)
Unemployed	0	1 (10%)	n=1 (5%)
Retired	4 (40%)	5 (50%)	n=9 (45%)
Other	0	1 (10%)	n=1 (5%)

The demographic data reveals varied experiences among the participants living with achalasia. A majority of the participants 45% (n=9) had been diagnosed with achalasia for over 5 years, with 40% (n=8) having been diagnosed for over 1 year, and a smaller fraction 15% (n=3) having been diagnosed for less than 6 months. Concerning strategies to aid eating in social settings, a significant portion of participants 75% (n=15) had attempted various interventions, while 25% (n=5)had not pursued any specific strategies. When considering the frequency of eating out, participants demonstrated diverse habits, with twice a month being the most common frequency 30% (n=6), followed by once a month 25% (n=5) and three times a month 20% (n=4). Relatively fewer participants reported eating out twice a week 10% (n=2), four times a month 10% (n=2), or six times a month 5% (n=1). In terms of enjoying eating in social settings, 60% (n=12) of participants reported currently enjoying it, while 30% (n=6) did not, and 10% (n=2) were uncertain.

Table 2. Baseline measures (n=20)

Variable	**Non-Completers**	**Completers**	**Total**
Number of participants	10	10	20
	Demographics		
Length of time since diagnosis			
<6 months	3 (30%)	0	n=3 (15%)
>1 year	4 (40%)	4 (40%)	n=8 (40%)
>5 years	3 (30%)	6 (60%)	n=9 (45%)
Have they tried anything to help them eating in a social setting			
Yes	7 (70%)	8 (80%)	n=15 (75%)
No	3 (30%)	2 (20%)	n= 5 (25%)
How often do they eat out			
Very little if at all	0	1 (10%)	n=1 (5%)

Twice a week	1 (10%)	1 (10%)	n=2 (10%)
Once a month	1 (10%)	2 (20%)	n=3 (15%)
Twice a month	3 (30%)	3 (30%)	n=6 (30%)
Three times a month	4 (40%)	0	n=4 (20%)
Four times a month	1 (10%)	2 (20%)	n=3 (15%)
Six times a month	0	1 (10%)	n=1 (5%)
Do they currently enjoy eating in social setting?			
Yes	6 (60%)	6 (60%)	n=12 (60%)
No	3 (30%)	3 (30%)	n=6 (30%)
Don't know	1 (10%)	1 (10%)	n=2 (10%)

Baseline characteristics of participants

Table 3 presents the comparison of data collected for all 20 participants at baseline, irrespective of completion status. The variables assessed included enjoyment, confidence, pleasure, and various symptoms related to eating in a social setting. For enjoyment, both groups exhibited similar average scores, with a mean of 3.4 (SD = 1.09) across all participants. Likewise, no difference was observed in confidence levels, with an average score of 3.05 (SD = 1.04) for all participants. In terms of pleasure, participants reported an average score of 3.5 (SD = 1.27), indicating a moderate level of pleasure associated with eating in social settings.

However, variability was noted in symptom experiences. On average, participants reported a moderate level of pain (M = 2.55, SD = 1.07), regurgitation (M = 2.25, SD = 1.39), and heartburn (M = 1.93, SD = 1.18). Additionally, participants reported experiencing nervousness (M = 3, SD = 1.28), stress (M = 3.1, SD = 1.03), and anxiety (M = 3.25, SD = 1.19) to a moderate extent.

These findings suggest that participants, regardless of completion status, exhibited similar baseline characteristics in terms of enjoyment, confidence, pleasure, and symptoms related to eating in social settings. Further analysis is needed to explore the effectiveness of the intervention in modifying these baseline measures.

Table 3. Comparing the data collected for both completers and non-completers at baseline.

Variable	**Non-completers**		**Completers**		**Total**
	n= (range)	Mean (SD)	n= (range)	Mean (SD)	Mean (SD)
Enjoyment	n=10 (2-4)	3.2 (0.92)	n=10 (1-5)	3.6 (1.26)	3.4 (1.09)
Confidence	n=10 (1-4)	2.7 (1.06)	n=10 (2-4)	3.4 (0.84)	3.05 (1.04)
Pleasure	n=10 (1-5)	3.2 (1.13)	n=10 (1-5)	3.8 (1.40)	3.5 (1.27)
Symptoms					
Pain	n=10 (2-4)	2.8 (0.79)	n=10 (1-4)	2.3 (1.34)	2.55 (1.07)
Regurgitation	n=9 (1-5)	3.4 (1.33)	n=10 (1-4)	2.1 (1.45)	2.75 (1.39)
Heartburn	n=8 (1-3)	1.87 (0.83)	n=10 (1-5)	2 (1.41)	1.94 (1.18)
Nervous	n= 10 (1-5)	3.2 (1.32)	n=10 (1-5)	2.8 (1.23)	3 (1.28)
Stressed	n=10 (3-5)	3.7 (0.82)	n=10 (1-5)	2.5 (1.18)	3.1 (1.03)
Anxious	n=8 (3-5)	3.7 (0.89)	n=10 (1-5)	2.8 (1.13)	3.25 (1.19)

In Table 4, the pre- and post-intervention data are presented, detailing participants' experiences before and after the intervention across various variables. While mean changes are provided, it is important to note the constraints imposed by the small sample size and the absence of statistical significance. Post-intervention, there was a slight decrease in enjoyment (mean change of -0.5) and pleasure (mean change of -0.3) related to eating in social settings, alongside modest improvements in confidence (mean change of 0.2). However, these changes should be interpreted cautiously, given the considerable variability observed in participant responses, as indicated by the standard deviations. Similarly, changes in symptoms post-intervention varied, with some symptoms showing slight decreases (e.g., regurgitation, nervousness) but also exhibiting notable variability.

Qualitative data from interviews confirmed the questionnaire findings, indicating that the workbook intervention positively influenced participants' eating behaviour in social settings. All five participants reported increased confidence and a shift in focus from finishing their meal to enjoying others' company. Participants described the workbook as "very useful," "informative," and a "confidence builder." According to the results of the pre-and post-questionnaire, which aimed to measure the impact of the workbook intervention on individuals' eating behaviour in a social setting, three respondents reported a positive impact, four were uncertain, and three were reported no impact.

Table 4. Eating in a social setting and the level of pleasure, confidence and enjoyment before and after the intervention (completers)

Variable	**Pre-intervention**		**Post-intervention**		
	n= (range)	Mean (SD)	n= (range)	Mean (SD)	Mean change
Enjoyment	n=10 (1-5)	3.6 (1.26)	n=10 (1-5)	3.1 (0.99)	-0.5
Confidence	n=10 (2- 4)	3.4 (0.84)	n=10 (2-5)	3.6 (0.97)	0.2
Pleasure	n=10 (1-5)	3.8 (1.40)	n=10 (2-5)	3.5 (0.97)	-0.3
Symptoms					
Pain	n=10 (1-4)	2.3 (1.34)	n=10 (1-3)	2 (0.82)	-0.3
Regurgitation	n=10 (1-4)	2.1 (1.45)	n=10 (1-4)	1.6 (1.07)	-0.5
Heartburn	n=10 (1- 5)	2 (1.41)	n=10 (1-4)	2 (1.05)	0
Nervous	n=10 (1-5)	2.8 (1.23)	n=10 (1-4)	1.8 (0.92)	-1

Stressed	n=10 (1-5)	2.5 (1.18)	n=10 (1-4)	1.6 (0.97)	-0.9
Anxious	n=10 (1- 5)	2.8 (1.13)	n=10 (1-4)	1.8 (0.92)	-1

Usability of the intervention

Participants provided feedback on the clarity and level of difficulty of the workbook activities in the post-intervention questionnaire. Of the ten participants who completed the workbook, nine reported the activities easy to understand, with one expressing uncertainty. Similarly, when asked about the ease of completion of the workbook activities, eight participants responded positively, while two were uncertain. As part of the post-intervention questionnaire, participants were also asked about the impact of the workbook on their ability to enjoy and feel comfortable eating in a social setting. Out of the 10 participants, six reported a positive impact, three were unsure, and one reported a negative impact as they were unable to apply the activities of the workbook in many instances. Participants were asked about the potential efficacy of the workbook in assisting people living with achalasia at any stage following their diagnosis. Of the ten participants, seven answered positively, two reported a negative response, and one was unsure about the potential benefits of the workbook intervention. Among the two participants who reported a negative response, one mentioned that the workbook would be helpful to those who were newly diagnosed with achalasia and the second participant said that when achalasia is severe, this workbook might be overwhelming or less beneficial. Participants were asked about their ability to complete the workbook activities independently in the post-intervention questionnaire. Nine confirmed their capability to do so, while one reported their inability to complete the workbook activities independently and noted that drawing on advice from others was helpful.

In the pre-intervention questionnaire, participants were asked to retrospectively assess the frequency of eating in a social setting over the past month. The same question was posed in the post-intervention questionnaire. Of the ten completers, four participants reported an increase in eating in a social setting and an intention to increase their engagement in social setting occasions following their use of the workbook. Three participants reported no change in the frequency of eating in a social setting , while three others stated that the frequency in which they ate in a social setting had not changed after completing the intervention.

APEASE

This section presents the findings from the feasibility assessment, narratively presented using the APEASE criteria. The data was obtained from the interviews and participant quotations, identified by a participant number, are provided to illustrate key concepts.

Acceptability

Participants' perceptions of the workbook's acceptability were explored during the interviews. A few participants highlighted that the intervention would be more acceptable if introduced earlier in the course of their condition or during the waiting period for a medical treatment. One participant stated, "*It would be more useful for someone in the early stages of the condition*" (participant 1), while another participant mentioned, "*I wish this workbook had been available to me then, because I found it very comprehensive*" (participant 5). Additionally, a participant expressed retrospectively, "*If I went back to before my treatment, I would have found it a lot more helpful*" (participant 2). These findings suggest that the acceptability of the intervention may be influenced by the timing of its implementation.

Practicability

During the interviews, participants were asked to provide feedback on the practicability of the workbook. Two participants mentioned that the structure and content of the workbook were logically ordered and easy to follow, stating, *"It flowed. It flowed for me"* (participant 5), *"It's easy to follow the activities"* (participant 2). These comments suggest that the workbook's layout and design successfully facilitated engagement and adherence to the activities. This is an important factor in assessing the practicability of the intervention, as difficult or confusing self-directed interventions may not be feasible for individuals to implement in their daily lives. Overall, the positive feedback on the workbook's layout and design is promising in terms of its practicability as a potential intervention for people living with achalasia.

Effectiveness

Participants shared their perceptions of the intervention's effectiveness during the interviews. All participants believed the intervention was an effective tool for people living with achalasia, with some participants providing specific reasons for their positive views. For example, one participant commented on the invaluable nature of the signposting in the workbook ie helpline information, stating, "*Definitely, yeah, most most definitely. And I think where you've signposted at the back; the helpline. I think that's really invaluable, you know*" (participant 1). Another participant highlighted that the content was relatable when they used the intervention, *". I really do because it it's making you feel understood"* (participant 5). Participants also highlighted the positive impact the intervention had on their quality of life, stating, *"it gives you confidence"* (participant 5) and *"It also helps people to live their life to the full"* (participant 3). One participant noted that the intervention provided several different ideas and options, which could be revisited in case one approach did not work, *"You know you got somebody that's trying to help you and you think, right, I'll have to go. If something doesn't work, you can go back to the workbook because you've got several different ideas. So yes, I do think it would help definitely because there's not a lot of help and advice out there really"* (participant 2). These responses suggest that the workbook was perceived as an effective resource for managing achalasia and eating in a social setting.

Affordability

During the interviews, participants were asked about the affordability of the intervention, specifically the cost of printing and using it. Most participants did not consider the cost of printing to be a major issue, with one participant noting that "*I don't think that's a problem*" (participant 1). However, participants did mention potential barriers, such as not having a working printer and the preference for a shorter workbook with fewer pages. Nevertheless, participants expressed a willingness to pay for the intervention indicating that the affordability of the intervention was not a major concern. Overall, the findings suggest that the intervention is reasonably affordable and accessible for people living with achalasia.

Side-effects

Participants were also asked about the intervention's potential negative effects on people who completed it. While four participants expressed confidence in the intervention's safety, emphasising its provision of various strategies and options to alleviate symptoms, the viewpoints of the remaining participants remain impactful. One participant even described it as *"all positive"* (participant 5). However, one participant was unsure if there could be any negative effects, highlighting the importance of monitoring for any unintended consequences of the intervention. The following quote is from the participant that was not sure about the negative consequences of the workbook: *"I can't speak for others unfortunately, I don't know. I hope not, I hope"* (participant 3). The absence of explicit concerns raised by participants suggests a generally favourable perception of the intervention's safety. *Equity*

One participant expressed concerns regarding potential equity issues related to the language and accessibility of the workbook. They highlighted that the language used in the workbook might not be suitable for individuals who are not well-educated or whose first language is not English. Participant 2 commented, "*There's a lot of people who aren't very well educated or English is not their first language"* and *"Because when you first learning English, if somebody gave you this book. How many words would you recognise?"* This could create barriers for individuals who may not have the same level of literacy or language proficiency as others.

Recruitment and retention

The study collected recruitment data to assess the viability of participant recruitment and determine the recruitment rate (N recruited ÷ recruitment time [weeks]). (22) The recruitment rate for this study is 1.5. The recruitment was active for 91 days over 14 weeks, generating 21 eligible participants who consented to participate in this study. The pre-intervention questionnaire was completed by 20 participants (20/21, 95% retention). Post-intervention questionnaires were completed by 10 participants (10/20, 50% retention), and 5 participants showed interest in participating in an interview after completing the post-intervention questionnaire and intervention (5/10, 50%).

Overview of findings

In this study, participants completed a pre-intervention questionnaire and received the co-designed intervention, including activities and techniques. Half of the participants completed the post-intervention questionnaire, and some took part in a short interview. The findings illustrate that the workbook can help some individuals to change their eating behaviour and enjoy eating in a social setting. Using the APEASE assessment allowed the researchers to evaluate the appropriateness of the intervention. Overall, the participants in this study found the intervention, a workbook for people living with achalasia, to be acceptable, practical, effective, and affordable. They reported that the workbook was easy to follow, comprehensive, and flowed well. Participants believed the intervention could help people living with achalasia by providing them with new strategies and confidence to manage their symptoms. Participants did not report any notable negative side effects from completing the intervention. However, one participant expressed concerns about the suitability of the language used in the workbook for those who are not fluent in English or have lower levels of English literacy.

Participants who completed all three stages of this study i.e. 5 participants agreed that the co-designed workbook is an effective tool for building confidence and helping people enjoy eating in a social setting. These participants also experienced fewer negative symptoms such as pain, stress and anxiety after completing the intervention. The majority of participants believed that the workbook would be more useful if they received it soon after initially experiencing symptoms of achalasia. However, most of those who completed the workbook successfully expressed their intention to use the workbook and reflect on its contents in the future.

Discussion

To the authors' knowledge, this is the first study addressing achalasia that tests the feasibility of a co-designed intervention. The intervention aims to enhance confidence and pleasure in social eating while also reducing anxiety and stress for people living with achalasia. Research has identified that eating is one of the most challenging aspects of living with achalasia (6) and that this becomes more salient in a social setting. (17) The main goal of this study was to evaluate the feasibility of recruitment and retention along with the usability and acceptability of the intervention that is grounded in theory and supported by real-world data.

In the current study, the average age of participants in the completers group was higher than the non-completers group; there were also more women in the completers group. More participants in the completers group reported the use of different interventions before using the one for this study, therefore, indicating potential higher self-efficacy. These results are aligned with previous research that reports that older age, higher self-efficacy for the intended health behaviour, and female gender are associated with increased adherence to Internet-based interventions. (23,24,25)

The completers group in this study had been living with achalasia for longer than those in the non-completers groups. People who had the condition for longer may have had a higher level of readiness for change, and this is in line with the results of a pilot study conducted by Morton et al. Their study shows that there may be a link between changes in risk factors for chronic diseases post-intervention and confounding variables such as self-selection method of participant recruitment. The study shows that people who decided to participate may have been more open to change and this means that they are more likely to take part in the intervention. (26)

This finding suggests a potential positive impact of the intervention on an individual's confidence. However, it is important to note that this study was primarily a feasibility study with a small sample size. Therefore, the generalisability of these results is limited and we do not make broader claims about the effectiveness of the intervention based on these findings alone. To establish the robustness and generalisability of the intervention’s effects on confidence, future work can involve replicating this study with a larger and more diverse participant cohort. A larger sample size would enhance statistical power, allowing for more reliable conclusions to be drawn regarding the intervention’s ability to facilitate increased confidence in social setting contexts. Moreover, a larger study would permit the exploration of potential moderators or mediators that may influence the relationship between the intervention and confidence outcomes.

Completers of the intervention reported a reduction in their negative symptoms following the completion of the workbook. This finding suggests a potential association between the workbook activities and symptom improvement. However, it is important to acknowledge that various external factors may have influenced these outcomes. Notably, the participants were given flexibility in completing the post-intervention questionnaire, which introduces the possibility of different contextual influences on their responses. Furthermore, the issue of recall bias must be considered, as participants may not accurately remember their symptom experiences in social settings if the questionnaire was not completed immediately after such events. Consequently, caution is needed before drawing definitive conclusions regarding the efficacy of the workbook in positively altering participants' symptoms. Due to the complexity of each person's experience and the many ways in which symptoms manifest, it is important to thoroughly investigate circumstances, psychosocial factors, and the participants' engagement with workbook activities to deeply understand how the intervention may help reduce symptoms. Such research will help us understand the effects of the intervention in a more detailed way and make it easier to facilitate the development of tailored interventions that meet the specific needs of people with achalasia.

A notable observation is that over half of the participants in the completers group had been living with the condition for more than five years. Despite their extensive experience with various interventions throughout their journey, these individuals expressed a continued search for tools and strategies to help them in managing their condition. Importantly, participants emphasised the significance of making this co-designed intervention available at the early stages of their diagnosis and treatment pathway. The chronic nature of their condition highlights the persistent challenges faced by people living with achalasia and the ongoing need for effective interventions to alleviate their symptoms and improve their quality of life. The participants' desire for accessible and timely interventions highlights the importance of early intervention initiatives and the necessity for healthcare providers to provide comprehensive support from the initial stages of diagnosis. These findings emphasise the significance of addressing the needs of people living with achalasia and highlight the potential benefits of readily available interventions integrated into the early stages of their treatment journey. By ensuring the availability of effective interventions and support mechanisms, healthcare providers can contribute to enhancing the overall well-being and long-term outcomes of individuals navigating the challenges associated with achalasia.

Although most of those who participated and completed all three stages of the study reported that the workbook was beneficial and helped them change their behaviour in a social setting, the assumptions made are limited by the small sample size. Although interviews were arranged soon after the participants completed the post-intervention questionnaire, they were arranged around two weeks after they had completed the questionnaire. The time lag between workbook completion, the post-intervention questionnaire and the interview can affect recall of people's opinions and perceptions of the workbook.

The findings of our study bring forth a novel perspective regarding participant retention in research studies. While initial assumptions based on previous studies might have suggested a highly motivated population willing to engage in research activities, our results reveal that retention, rather than recruitment, emerged as a significant challenge. This insight underscores the importance of not only focusing on recruitment strategies but also implementing effective retention techniques to ensure continued participation throughout the study duration. These unexpected findings contribute valuable insights to the existing literature, highlighting the necessity for tailored approaches to promote sustained engagement among research participants. The current study used the Achalasia Action support group in order to recruit participants through emails that were sent by the moderator of the group. In this study, a retention rate of 50% was achieved which is comparable to the existing literature. For example, this falls within the range observed in a comprehensive literature review of web-based well-being interventions for informal caregivers of people living with dementia. The retention rates in these studies varied between 32.6% and 97.4%, with an average of 70.44%. These figures emphasise the variability in retention rates across different studies and interventions, highlighting the importance of contextual factors in influencing participant retention. (27) In a systematic review by Whitakar et al., it was evident that using social media such as Facebook not only aids in efficient recruitment but also fosters a more engaged participant community. This engagement might lead to improved retention and completion rates in studies. Recruiting through Facebook tends to be more efficient than traditional methods such as email or word of mouth. This will give the researcher the ability to connect to harder-to-reach populations. (28) Future studies may benefit from using social media channels such as Facebook groups for people living with achalasia as a way to reach out to a more engaged and active participant pool. This strategy may improve participant involvement and enable a greater understanding of the experiences related to achalasia.

Strengths and limitations

In testing the feasibility of the intervention, one of the inherent strengths was its co-designed nature, developed in a previous study. (17) This collaborative approach ensured that the intervention was initially tailored to meet the specific needs and experiences of those living with achalasia. However, while this tailoring is a potential strength, it is important to note that the primary focus of the current study was on the feasibility of implementing this pre-designed intervention rather than its co-design process. Participants in the study were members of the Achalasia Action Group, which is a forum that provides information and support for people living with achalasia. This shared understanding and mutual support within the group may have facilitated greater engagement and willingness to participate in the intervention, thereby enhancing the feasibility of the study.

The study acknowledges that the sample size was small, which is a characteristic typical of feasibility studies. It is important to note that this study is designed to assess the feasibility of recruitment and implementing a co-designed intervention rather than drawing conclusions on its efficacy. Although this is understandable given the rare nature of achalasia, a small sample size limits the generalisability of the findings and the study’s statistical power. Therefore, caution should be exercised in generalising the results to the wider population of people living with achalasia or those participating in support groups. Since the participants were all members of the Achalasia Action group, they shared similar experiences and characteristics related to their condition. This homogeneity may limit the diversity and variability of perspectives and behaviours within the study, potentially affecting the generalisability of the findings to a broader population of people living with achalasia. The study did not include a control group for comparison. Without a control group, it is challenging to determine the extent to which the co-designed intervention specifically contributed to changes in eating behaviours, as other factors, such as external influences, may have influenced the outcomes. The absence of a control group limits the ability to establish a causal relationship between the intervention and the observed changes. The study relied on self-report measures to assess changes in eating behaviours. Self-reported data are subject to recall biases, social desirability biases, and individual interpretations. These limitations may affect the accuracy and reliability of the reported outcomes, potentially compromising the validity of the findings.

Future work

Conducting a study with a larger sample size would provide more robust and representative findings. While the current study focused on participants from the Achalasia Action group, future research could aim to include participants with diverse demographic characteristics, such as age, sex, and cultural backgrounds. This would allow for a more comprehensive understanding of the feasibility and effectiveness of the co-designed intervention across different populations. Employing a randomised controlled design would strengthen the study’s ability to establish causal relationships between the intervention and changes in eating behaviours. By randomly assigning participants to an intervention group or a control group, researchers can more confidently attribute the observed effects to the intervention itself. Assessing the sustainability of changes in eating behaviours over an extended period would provide valuable insights into the long-term effectiveness of the co-designed intervention. Conducting follow-up assessments at multiple time points after the completion of the intervention can help determine whether the observed changes are maintained or diminish over time. By addressing these areas in future studies, researchers can further enhance the understanding of the effectiveness of this co-designed intervention to change eating behaviour in social settings for people living with achalasia.

Conclusion

The study successfully recruited to target and retained half of the participants at follow-up, indicating the feasibility of engaging people living with achalasia in the intervention. Based on the data from the interviews the intervention demonstrated usability and acceptability, as participants actively engaged and found it valuable. Participants reported positive experiences, suggesting potential effectiveness in changing eating behaviours in social settings. Moreover, applying the APEASE criteria provided further insight into the intervention’s impact on participants’ lives.. Despite the limitations, such as the small sample size, the study provides valuable insights into the feasibility of the recruitment and acceptability of the co-designed intervention. Overall, this study serves as a foundation for future research to pilot this intervention on a larger scale to change eating behaviours and improve the quality of life for people living with achalasia.

The findings of this feasibility study hold significant implications for both the field of achalasia research and the lives of people living with this condition. By exploring the feasibility of implementing a co-designed intervention targeting challenging eating behaviours in social settings, this study pioneers a novel approach to address the unique needs of people living with achalasia. This study contributes to the existing literature by shedding light on the potential effectiveness and practical considerations associated with such interventions. Ultimately, the successful development and implementation of tailored interventions have the potential to significantly enhance the quality of life for people with achalasia, empowering them to navigate social eating situations with greater confidence and improved outcomes.

List of abbreviations

COM-B model:	Capability Opportunity Motivation - Behaviour model
APEASE:	Affordability, Practicality, Effectiveness and cost-effectiveness, Acceptability, Side-effects/safety, Equity
LOS:	Lower Oesophageal Sphincter
BCT:	Behaviour Change Techniques
TDF:	Theoretical Domains Framework
BCW:	Behaviour Change Wheel
SD:	Standard deviations

Declarations

Ethics approval and consent to participate

A favourable opinion for conduct was given by the University of Reading School of Chemistry, Food and Pharmacy Research Ethics Committee (SREC 51/2022). All methods were carried out in accordance with the approval, and informed consent was obtained from all participants.

Consent for publication

Not applicable.

Availability of data and materials

The datasets generated and/or analysed during the current study are not publicly available because participants can be identified from them, but the anonymised data are available from the corresponding author upon reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Authors’ contributions

MK, AH, RL and MH made a substantial contribution to the design of the work. MK distributed the questionnaires and conducted the one-to-one interviews. MK, AH, and RL extensively discussed how to analyse and interpret the data. AH and RL contributed to and supervised the analysis of the collected data from the questionnaires and the interviews. All authors (MK, AH, RL and MH) revised the manuscript critically for intellectual content, agreed and approved the final version to be published.

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Chapter 6

6. Discussion

This chapter offers an integrated discussion of the research detailed in this thesis. The overarching aim of the thesis was to investigate the challenges faced by people living with achalasia. Based on the findings, a strategy was devised, primarily presented in the form of a workbook. It is essential to note that while the workbook is a singular intervention, it encompasses multiple elements or sub-strategies designed to enhance the quality of life for these people. This aim is explored through three key pieces of research.

6.1 Overview of thesis findings

This research journey, as outlined across the chapters, offers an illuminative exploration into the intricacies of living with achalasia. The first study, as detailed in chapter 3, ventured into the sequential stages that mark a people's encounter with this rare condition, giving us foundational insights. It went beyond a mere clinical lens, capturing the emotional, psychological, and social tribulations that accompany the medical challenges. Patient journeys are tools designed to gather data on patients' experiences across several medical specialities, including rare diseases. (118) They are simple methods available to highlight the needs of a patient community, which can complement the perspective of healthcare professionals regarding a particular disease if desired. This approach facilitates the sharing and exchange of information between patients and clinicians, encompassing not only medical aspects and the natural progression of the disease but also emotional, psychological, social, and other factors that influence daily requirements. It fosters discussions aimed at identifying unaddressed needs and tackling challenges to find potential solutions. These challenges or gaps in care may be common among a group of patients with a particular diagnosis, as well as specific to individual syndromes. (119) Patients with rare diseases often experience a significant delay in receiving the correct diagnosis, requiring multiple visits to various healthcare professionals. This prolonged diagnostic process can result in prolonged suffering and anxiety for these individuals, lasting for several years. (120) The process map developed in this study was specifically designed to chart the journey of people with this rare disease and highlight areas where additional support is crucial. Its structure not only provides a visual representation of their experiences but also points to potential sectors where healthcare professionals and support systems can make a significant difference. A fundamental global problem is raising the quality of care in an environment of growing complexity and reduced resources. (121) Recent evidence suggests that vulnerabilities in day-to-day medical practices (operational criticalities) and the broader healthcare infrastructure (system criticalities) are the leading causes of quality and safety issues in healthcare. (122) In order to increase quality and safety, healthcare systems have used tools and methods from industrial engineering during the past 15 years. (123) Process Mapping, also known as Process Modelling, is one such approach that focuses on the systems and processes that new interventions are introduced into. Process mapping may be utilised in Quality Improvement projects to better analyse present practice and develop improved procedures. (124) Antonacci et al. conducted a systematic review highlighting the benefits of process mapping in improvement initiatives and categorised them into three areas. Firstly, process mapping aids in understanding local systems by providing insight into complex healthcare dynamics. Secondly, it informs interventions' design, development, and evaluation, allowing for targeted improvements. Lastly, process mapping promotes co-production and knowledge exchange among stakeholders, fostering collaboration and facilitating the dissemination of best practices. This review emphasises the value of incorporating process mapping in healthcare quality improvement efforts, benefiting practitioners, researchers, and policymakers in optimising care delivery. (125)

Such a nuanced understanding was instrumental in the co-designing of the intervention presented in chapter 4. The primary aim of the second study was to identify and prioritise the challenges faced by people living with achalasia, particularly in the context of eating behaviours. As a result, an intervention was specifically co-designed to address a primary challenge identified by people living with achalasia which was eating in a social setting. This intervention, tailored to the unique challenges of achalasia, characterises the principles of patient-centric care. Central to the philosophy of this research is the value and importance of collaborative design. Kleinsmann and Valkenburg (2008) highlight the significance of involving different people within a co-design process. They emphasise that every individual brings specific knowledge to promote shared understanding to help achieve the larger common objective, which can be a new product, service or system. Each person can contribute their unique set of talents and limitations to the co-design process. (126) When conducting a co-design study, it is important that the researcher does not take a very dominant role and embrace a supporting role to aid the initiation of collaboration. The aim of these kinds of studies is to achieve a symbiotic collaboration which can be a beneficial relationship between different groups of people. (127) Co-design enhances consumer engagement, provider-consumer interactions, and service quality. (128) Making end-users' or consumers' lived experiences central throughout the project's lifespan is the key to effective co-design. (129) This philosophy resonates strongly with the aims and findings of our co-design phase, which underscored the effectiveness of approaches that centre on the patient.

The subsequent evaluation in chapter 5 underscored the potential of such bespoke, patient-centric interventions in enhancing the quality of life for people living with achalasia. The aim of the feasibility study was to test the practicality and potential efficacy of the intervention in real-world conditions, thus building upon the insights gained from the co-design process. However, it was necessary to assess whether this intervention could be effectively implemented. The study primarily aimed to test the feasibility of implementing the intervention and pilot measures to gauge its potential efficacy. Feasibility studies serve the purpose of evaluating the suitability of an intervention for further investigation. They provide researchers with the opportunity to assess the relevance and sustainability of their ideas and findings, determining if they can be effectively developed and pursued. (130) A feasibility study also evaluates the viability of conducting a randomised controlled trial (RCT). (131) Feasibility studies typically do not evaluate project outcomes, (132) while researchers often neglect the economic aspects, they provide statistical analysis of clinical efficacy. (131) This creates an ambiguity in the understanding of policymakers and potential funders of the trials conducted on a larger scale. Furthermore, this implies that any subsequent publication lacks relevant information regarding cost-effectiveness. Hence, it is not feasible to directly compare the collection of cost and quality-of-life data across various feasibility studies. (131) On the other hand, such research has the potential to identify any necessary modifications to the research methods or protocols, as well as provide insights into the possible implementation of these changes. (130) Feasibility studies encompass a range of essential areas that help evaluate the viability of an Intervention. The evaluation of the intervention spans multiple domains. Acceptability focuses on the reactions of both recipients and implementers to the intervention. Demand assesses the potential or actual uptake of the intervention in a given population or setting. In the realm of implementation, the emphasis is on determining if the intervention can be executed as planned. Practicality delves into the feasibility of delivering the intervention when faced with resource or time constraints. Adaptation explores the necessary modifications to the intervention to make it suitable for different contexts or populations. Integration weighs the systemic changes required to embed the intervention into existing infrastructure. Expansion considers the potential success when the intervention is applied to other populations or settings. Lastly, limited-efficacy testing conducts preliminary evaluations of the intervention, usually with specific sample sizes or over shorter follow-up durations. By considering these areas, researchers can gain valuable insights into the feasibility and effectiveness of their interventions and make informed decisions for further development and implementation. (130)

The key findings of the three studies on achalasia hold significant implications for both clinical practice and future research endeavours. Firstly, by delineating distinct phases in patients' journeys and identifying key challenges faced before and after diagnosis, the first study lays the groundwork for targeted behaviour change interventions aimed at supporting long-term management. This underscores the importance of personalised care approaches that address the unique needs and experiences of individuals living with achalasia. Secondly, the development of an intervention targeting eating in social settings in the second study represents a pioneering effort to address a specific and challenging aspect of achalasia management. By highlighting the importance of social support, stress reduction strategies, and proactive planning, this intervention offers a holistic approach to enhancing the quality of life for individuals living with achalasia. Moreover, the successful feasibility and acceptability demonstrated in the third study suggest that such interventions are not only practical but also well-received by patients. This underscores the potential effectiveness of tailored interventions in facilitating behaviour change and improving patient outcomes. In terms of future practice, these findings advocate for the integration of personalised interventions into standard care practices for achalasia, emphasising the importance of addressing both physical and psychosocial aspects of the condition.

The research journey, spanning three comprehensive studies, unveiled several pivotal findings related to the experiences of people living with achalasia. The combined results of these studies underscore the crucial need for a holistic approach when tackling rare conditions such as achalasia. Instead of solely focusing on clinical symptoms, it is important to consider the wider lived experiences of people. Furthermore, the research underscores the power of collaborative tools like process mapping, not just as methodological instruments but as vital frameworks to genuinely comprehend and cater to patient needs.

6.2 Implications for research

The thesis fills a gap in existing research on achalasia by focusing on patients' experiences, an area often overlooked in previous studies primarily concentrating on clinical outcomes. Through participatory action research involving patients, this study ensures its findings are relevant and meaningful to those living with the condition. Additionally, by exploring how individuals cope with their condition and symptoms, the research goes beyond clinical observations, offering valuable new insights. This work significantly contributes to our understanding of achalasia, providing a more holistic view of the condition and its impact on patients' lives. The use of process mapping to understand the patient journey provides a valuable framework for future research. This approach could be applied in studies exploring patient experiences in other rare or chronic conditions, helping to identify key challenges and intervention points. Rare diseases often present significant diagnostic challenges, with patients frequently experiencing prolonged periods of uncertainty, multiple misdiagnoses, and delays in receiving the correct diagnosis. (120) By understanding the patient journey, researchers and healthcare providers can identify common roadblocks or missteps and work to address them, thereby expediting the diagnostic process and reducing the associated emotional and psychological stress for patients.

One of the key elements of this research was the co-design of an intervention with patients. This approach underscores the value of involving patients directly in research, especially in areas that intimately affect their daily lives. This could encourage broader adoption of participatory research designs in future studies, not just in achalasia but in other rare chronic conditions as well. The findings of this thesis emphasise a pressing need to incorporate patients' quality of life and social interactions into the core of medical research, signalling a shift towards a more holistic understanding of patient well-being. This paradigm shift can lead to the development of comprehensive frameworks that recognise the intertwining nature of medical, social, and psychological aspects of managing chronic diseases. Such an approach necessitates interdisciplinary collaboration, inviting medical researchers, social scientists, and policymakers to jointly explore solutions that cater to the multifaceted needs of patients with rare chronic diseases. Research conducted with this holistic perspective can better inform policy decisions, ensuring healthcare systems holistically address patients' needs. Simultaneously, educational initiatives should be developed, targeting healthcare professionals and the general public, promoting an understanding that patients are much more than the sum of their symptoms. In essence, this comprehensive lens can guide the evolution of healthcare research, policy, and practice, ensuring both the medical and socio-psychological needs of patients are met.

The feasibility study that assessed the co-designed intervention is a testament to the critical role of preliminary research in health interventions. Before implementing any new intervention, such research can serve as a benchmark, ensuring that the intervention is built on a solid foundation, tailored to its intended audience, and designed with the necessary considerations in place.

This research also identifies the need for further interventions to address the other challenges that people living with achalasia face daily. This research has illuminated not just the challenges associated with social eating experiences but has also shed light on a broader spectrum of difficulties faced by people living with achalasia. From the initial symptoms and diagnosis phase to the long-term management of the condition, people living with achalasia encounter a variety of obstacles that impact their daily lives. For instance, understanding the nuances of the condition, coping with psychological stress, managing physical discomfort, and navigating healthcare systems are all areas that merit deeper investigation. While the co-designed intervention in this study is a step in the right direction, it is evident that a single intervention cannot address the entirety of the challenges that these people face. Hence, there is a pressing need for subsequent research initiatives that delve deeper into each specific challenge, providing a more holistic approach to care.

This research marks a turning point in achalasia studies. For the first time, a comprehensive map detailing the specific journey of an achalasia patient has been charted, integrating a robust patient-centric focus. This holistic approach led to the identification of vital intervention areas, such as the long-term management of achalasia. A notable breakthrough is the co-designed intervention addressing challenges faced during eating in a social setting, which, when tested, showed promising initial results. Beyond merely highlighting the care and support gaps in the field, this work offers a pioneering roadmap built upon comprehensive viewpoints. This roadmap serves as an essential guide for future researchers and practitioners, reinforcing the importance of addressing the multifaceted challenges encountered by those living with achalasia.

6.3 Implications for practice

The research findings underscore significant gaps in the current care of individuals living with achalasia, urging healthcare providers to implement targeted interventions and strategies for improvement. One of the primary challenges identified is the diagnostic journey, characterised by delays. To address this, healthcare systems should prioritise standardising diagnostic protocols and enhance clinician awareness of achalasia's symptoms and diagnostic criteria. By streamlining the diagnostic process, patients can receive timely confirmation of their condition, leading to quicker access to appropriate care and management.

Beyond the initial diagnosis, the study emphasises the necessity of comprehensive long-term management plans tailored to the unique needs of achalasia patients. These plans should extend beyond medical interventions to encompass holistic support, including dietary guidance, psychological counselling, and social support networks. Such interventions aim to enhance patients' quality of life by equipping them with the necessary tools and resources to navigate the challenges posed by achalasia effectively.

Central to effective management is patient education, which plays a vital role in empowering individuals to actively participate in their care. Healthcare providers should prioritise patient education initiatives aimed at imparting practical coping strategies for daily challenges, such as mealtime difficulties and dietary modifications. By providing patients with the knowledge and skills to manage their condition autonomously, healthcare providers can foster a sense of empowerment and self-efficacy among achalasia patients.

Moreover, promoting patient-centred care is paramount in ensuring that interventions align with patients' values, preferences, and lifestyles. This entails actively involving patients in decision-making processes and co-designing interventions collaboratively. By prioritising patient autonomy, healthcare providers can foster a sense of partnership and mutual respect, ultimately enhancing patient satisfaction and treatment adherence.

Building trust and fostering transparent communication between patients and healthcare providers are foundational elements of effective care delivery. Healthcare professionals should cultivate an environment of open dialogue, empathy, and respect, where patients feel heard, valued, and supported. By prioritising patient-provider relationships built on trust and mutual respect, healthcare providers can enhance patient engagement, satisfaction, and overall healthcare outcomes.

The findings from this research highlight actionable recommendations for improving the care of individuals living with achalasia. By implementing targeted interventions focused on streamlining diagnosis pathways, enhancing long-term management, promoting patient education, and fostering patient-centred care, healthcare providers can significantly enhance the quality of life and well-being of Achalasia patients. Continued collaboration among researchers, healthcare providers, and policymakers is essential to drive meaningful improvements in achalasia care and ensure that individuals receive the comprehensive support and resources necessary to thrive.

6.4 Personal reflexivity

My involvement in this research and the planning of my studies as a pharmacist starting a PhD study on people living with achalasia have been significantly influenced by my professional background and experiences. Being a pharmacist has given me a variety of perspectives and insights that have influenced how I approach research. Achalasia is a relatively rare condition, and as a pharmacist, I may not encounter it frequently in our day-to-day practice. However, even though direct exposure to achalasia cases may be limited, there are still ways in which being a pharmacist can contribute to the research and design of studies on this condition. Pharmacists often play a crucial role in patient counselling and education. Although I may not encounter achalasia cases directly, my experience in counselling patients with other digestive disorders or chronic conditions can provide insights into effective communication strategies, patient education materials, and promoting self-management skills. These skills can be applied to develop interventions that enhance patient understanding and coping mechanisms specific to achalasia. Interacting with patients in a clinical setting has given me valuable insights into their perspectives, needs, and aspirations. These insights have influenced my decision to focus on the social aspect of eating behaviour as a key area for intervention. By drawing on my interactions with patients, I aimed to design an intervention that not only addresses the physical symptoms but also addresses the emotional and psychological aspects of living with achalasia. While my professional background undoubtedly brings valuable insights, I am also aware of the potential biases it might introduce. To address this, I actively engage in reflexivity throughout the research process. I maintained a reflexive journal, documenting my thoughts, emotions, and reflections to critically analyse my own biases and assumptions throughout my PhD. I sought feedback and input from colleagues, advisors, supervisors and experts in qualitative research to challenge my perspectives and enhance the rigour of my study. By transparently acknowledging the potential impact of my pharmacist identity, I aspire to conduct my research in a reflexive and ethical manner. I am conscious that total neutrality may be unattainable due to the subjective nature of qualitative research. However, I continually aim to critically examine and manage these potential influences throughout the research process to uphold the integrity of my studies. Pharmacists are well-versed in ethical principles, patient confidentiality, and regulatory requirements concerning research and patient data protection. This knowledge ensures that my study adheres to the necessary ethical guidelines and legal requirements, safeguarding participant rights and privacy. I recognise the importance of balancing my professional knowledge with an open mind, ensuring that my research is driven by the voices and experiences of the participants rather than my own assumptions. Overall, my journey as a pharmacist has significantly influenced my involvement in this research and the design of my studies. By combining my subject matter expertise, clinical experiences, and access to healthcare settings, I aimed to contribute to the field of achalasia research and ultimately improve the lives of people living with this condition. In reflecting on my thesis, I also recognise the importance of acknowledging the gap in knowledge among healthcare practitioners highlighted through my work. This underscores the necessity for ongoing education and training initiatives to ensure healthcare professionals are equipped to provide patient-centred care effectively. Moreover, I acknowledge the role patients can play in their own education and management of their conditions, emphasising the need for collaborative efforts between healthcare providers and patients to optimise outcomes.

My personal philosophical perspective is firmly rooted in a humanistic worldview and guided by principles of care ethics when I approach my research on people living with achalasia. Care ethics emphasises empathy, responsibility, and relational understanding, aligning with my goals of patient-centred research. I firmly believe that every person has inherent worth and dignity, and I am motivated by a desire to make life better for those who are dealing with the challenges of achalasia.

From my standpoint, the reality is complex and multifaceted, including not only physical symptoms but also emotional and social dimensions. I view the creation of knowledge as a dynamic process that results from dialogue and interaction with patients, supervisors and colleagues. I value people’s lived experiences because I know that their distinctive viewpoints are essential to understanding the true effects of achalasia on their lives. I follow the ethical tenet of patient empowerment and autonomy. I support creating a working relationship with patients, actively involving them in decision-making, and respecting their right to make well-informed healthcare decisions. This perspective is particularly relevant to people living with achalasia, who often face challenges related to eating and socialising. Drawing upon the principles of bioethics and social justice, I aim to design interventions that not only address the physical symptoms of achalasia but also enhance patients’ overall well-being and quality of life. I am well aware of the significance of taking into consideration the larger social, cultural, and economic contexts that influence the experiences of people living with achalasia. Throughout my research journey, my philosophical perspective has influenced my decisions and actions. It has influenced the formulation of research questions that give patients’ viewpoints and needs top priority, as well as the design of interventions that concentrate on the social determinants of eating behaviour.

By acknowledging and addressing the emotional and psychological impact of achalasia, I seek to support patients in navigating their journey with dignity and resilience. I acknowledge that there may be alternative philosophical perspectives and critiques regarding the conceptualisation of achalasia and the design of interventions. In conclusion, my research on people living with achalasia is informed and directed by my unique philosophical perspective, which is based on humanistic principles, an ethical code of care, and social justice principles. I work to produce insights that can have a positive effect on the lives of people who are affected by this difficult condition by adopting a collaborative and patient-centred approach.

6.5 Strengths and limitations

While this thesis offers pioneering insights through an interdisciplinary lens, it is essential to acknowledge both its strengths and limitations, detailed in the corresponding chapters. The utilisation of an interdisciplinary approach within this research reflects a significant shift from the traditional approach to health-related research. By combining medical research with social studies, this thesis broadens the lens through which achalasia is understood and addressed. This enables a more nuanced appreciation of the complexities of the condition, incorporating the biological, psychological, and sociocultural aspects of the patients' lived experiences. It underscores the importance of comprehensive patient-centred care and encourages further interdisciplinary collaboration in the field. The practical implications of this research bear considerable significance. By undertaking an in-depth examination of the patient journey and designing interventions directly addressing the challenges identified, this research is set to have a real-world impact. This marks a departure from research purely focused on theoretical understanding; instead, it offers tangible solutions that could make a profound difference in patients' quality of life. Additionally, it sets a precedent for future research to focus on applied outcomes, thereby contributing to the evolution of patient care practices. The patient-centred co-design method employed in the second study is a major strength. This approach empowers patients, acknowledging them as experts in their own experiences, and thus central to the design of the intervention. By giving them an active role in designing the intervention, their unique insights and needs directly shaped the output. This makes the intervention more aligned with their requirements and experiences, enhancing the acceptability and likely efficacy of the intervention.

Furthermore, this approach reinforces the notion of patient autonomy and self-management, important concepts in contemporary healthcare. The inclusion of a feasibility study in this research illustrates methodological robustness. By evaluating the practicality of the intervention prior to wider implementation, potential pitfalls and areas for refinement were proactively identified. This allows for adjustments to be made early, improving the chances of the intervention being successful when implemented on a larger scale. It also offers a realistic view of the intervention's potential for integration into routine care or daily life. This adds a layer of practical foresight to the research, increasing its reliability and potential impact.

The research in this thesis, like many health-related studies, could be limited in terms of generalisability. The specific characteristics and experiences of the sample may not fully represent the wider population of people living with achalasia since they were all recruited from a support group within the UK. Factors such as age, sex, ethnicity, socioeconomic status, and severity of the condition can vastly influence patient experiences and treatment outcomes. The homogeneity of the sample may raise questions about the generalisability of the findings to more diverse populations. Since the study's conclusions are based on this specific demographic, caution should be exercised when applying these findings to populations with different demographic profiles. It is essential to recognise that the experiences and perspectives of individuals from various demographic backgrounds may vary, potentially influencing the outcomes observed in the study. Moreover, the overrepresentation of certain demographic groups, such as women and individuals of a specific racial or ethnic background, may introduce biases that could affect the interpretation of results. For instance, the experiences and behaviours of women may differ from those of men, leading to skewed or incomplete insights if not adequately addressed. Most of the participants in this research were of a similar background and had access to similar resources and support. Therefore, the process map and the co-designed intervention developed in the studies in this thesis might not cater to the needs of every people living with achalasia. Another potential limitation of this study pertains to the sample selection. Participants were self-selected, which might introduce selection bias, as those who volunteered could inherently possess characteristics or experiences that differentiate them from the wider achalasia patient population. Furthermore, this study was geographically constrained, with participants limited to those residing in the UK. As such, the findings might be particularly reflective of the care systems and cultural context of the UK. It is acknowledged that care systems, patient experiences, and socio-cultural influences can vary considerably across countries. Therefore, while the findings provide valuable insights into the patient journey and potential intervention areas specific to the UK, caution should be exercised when generalising these insights to global contexts. Nonetheless, the research methodologies and the foundational roadmap developed can serve as a template for similar studies in different geographical or cultural settings, encouraging a broader international exploration in the future. While the patient-centred co-design process is one of the strengths of this study, it also introduces potential bias and subjectivity. Patient input might be influenced by personal experiences, expectations, and cognitive biases, which could impact the objective development of the intervention. Additionally, patients might lack specific knowledge about the full range of possibilities for intervention or potential medical contraindications, limiting the design process.

Feasibility studies are invaluable in assessing the practicality of interventions. However, they are not always predictive of long-term success or effectiveness. The third study may not fully account for real-world complexities that could influence the intervention's implementation and effectiveness in a broader context. Factors such as participants' motivation, adherence to the intervention, access to resources, and varying social contexts might affect the long-term utility of the intervention. The studies in this thesis relied heavily on self-reported data; this could introduce biases related to memory recall, misinterpretation of questions, or social desirability. The accuracy and validity of self-reported data can vary depending on these factors, which could impact the reliability of the findings. One of the primary modes of data collection in this study was online, which presents its own set of advantages and challenges. On the one hand, online data collection can be a strength as it often allows for a larger and more geographically diverse sample, can be cost-effective, and may offer participants a feeling of anonymity, potentially leading to more candid responses. Furthermore, in the digital age, online methodologies can cater to the preferences and conveniences of many participants, particularly younger demographics. On the other hand, online data collection can have limitations as there is potential for a lack of control over the environment in which the participant responds, which can introduce variables that would not exist in a controlled setting. There might also be a potential bias towards participants who are more technical or have reliable internet access, potentially excluding certain demographics. Moreover, without face-to-face interactions, nuances in participant reactions or feelings might be missed, and there's a higher likelihood of misinterpretation of questions. Incorporating other data collection methods, such as direct observation, medical records, or third-party reports, could provide a more robust and comprehensive view of the patient journey and the effectiveness of the intervention.

6.5 Future work

Based on the knowledge gained from this study, it is crucial to develop a forward-looking plan that not only expands upon our existing discoveries but also takes into account the changing field of achalasia research and the needs of people living with achalasia. By categorising the goals into short-term, medium-term, and long-term timeframes, a methodical approach can be taken to tackle the various aspects of this situation and the difficulties it presents.

6.5.1 Short-term goals

In the immediate aftermath of the research in this thesis, a short-term focus can illuminate the path forward. It is apparent that the utilisation of qualitative research approaches would provide a more comprehensive exploration of people’s lived experiences. Such an approach promises to look beyond mere symptoms, enriching our understanding of the broader impacts on areas like family, careers, and mental well-being. Simultaneously, there is a pressing need to implement the pilot study on a more extensive scale. Capturing a diverse range of patient demographics is essential. By understanding varied contexts, we not only refine our research design but also bring our findings closer to universal applicability. Additionally, a holistic approach that encompasses the physical and socio-psychological aspects of living with achalasia should be infused into regular practice. The co-designed interventions from this study, when integrated into standard care, symbolise a promising shift from pure theoretical insights to tangible, life-altering solutions.

6.5.2 Medium-term goals

For the medium term, a careful analysis of the numerous challenges caused by achalasia is necessary. Although our research has elucidated several challenges encountered by individuals diagnosed with achalasia, compiling an exhaustive list remains a complex endeavour. Delineating these issues and then systematically designing interventions will close the gap between patient demands and the solutions that are currently being offered. The incorporation of interdisciplinary expertise is crucial to our medium-term plan. The co-design process can be improved by collaborative efforts that draw insights from several academic and clinical fields, producing solutions that are both novel and efficient.

6.5.3 Long-term goals

As the path forward unfolds, the long-term goal becomes evident. The research underscores the essential need for comprehensive and ongoing support services for people living with achalasia, which go beyond mere medical treatments. Based on the findings of this thesis ,future initiatives should include regular follow-ups, funded support groups, counselling, and accessible resources to manage the psychological and social challenges associated with the condition. A holistic approach, capturing not only the physical but also the social and psychological facets of living with achalasia, suggests that interventions like the one co-designed in this study could become integral components of standard care practices.

Moreover, achieving a global impact remains a cornerstone of this long-term vision. While the current research is predominantly situated in the UK context, there is a pressing need to expand inquiries to broader international horizons. The methodology and conceptual framework established in this study can serve as foundational guides for investigations in other geopolitical and cultural settings. Challenges such as participant motivation, adherence to interventions, resource availability, and the complexities of diverse social contexts need consideration. Extended follow-up studies in various settings will be pivotal in assessing the long-term sustainability and adaptability of the interventions, aiming to cater to the diverse needs of achalasia patients worldwide.

6.6 Conclusion

This research has significantly contributed to the field of achalasia management, providing an in-depth understanding of a patient's journey from diagnosis to living with the condition long-term. The research identified the challenges faced by people living with achalasia, especially concerning enjoying meals in social settings, a fundamental aspect of human interaction. In response to these challenges, a novel approach was taken by co-designing an intervention specifically with people living with achalasia. This empowers patients, giving them a voice and active role in shaping solutions to the problems they experience, which in turn increases the likelihood of the intervention's acceptance and effectiveness.

The co-designed intervention was successfully tested for its practicability in the initial stages of the study and shows potential to enhance patients' social eating experiences and overall quality of life. It has demonstrated that interventions developed with an intimate understanding of the patient journey, driven by patient insights, have the potential to provide real-world solutions. Furthermore, the study highlights a shift in perceptions needed in the care of achalasia patients. Instead of solely focusing on medical management, it advocates for a more holistic, patient-centred approach where patients' social and psychological needs are also addressed.

Moreover, this research highlights the significance of behaviour and environment in managing a medical condition such as achalasia. It showcases that by changing certain behaviours and creating an understanding environment, we can significantly improve the lives of those living with achalasia.

This research embodies a transformative stride in the domain of achalasia care, elucidating a deeper understanding of patient experiences and advancing management strategies. A distinguishing aspect of this work lies in its novel approach to co-design. While co-design theory and practice are multifaceted, our methodology was distinctively informed by the integration of the COM-B model and the Theoretical Domains Framework (TDF). This theoretical foundation ensured that the interventions were not only tailored to the unique challenges faced by achalasia patients but also rooted in established behavioural and cognitive paradigms. Furthermore, our emphasis on patient and public involvement championed the authenticity and relevance of our co-designed interventions, underscoring their potential to enhance patients' quality of life. As a consequence, this research stands as an exemplar for further studies in achalasia care, advocating for a more patient-centric and theory-driven approach in managing the condition.

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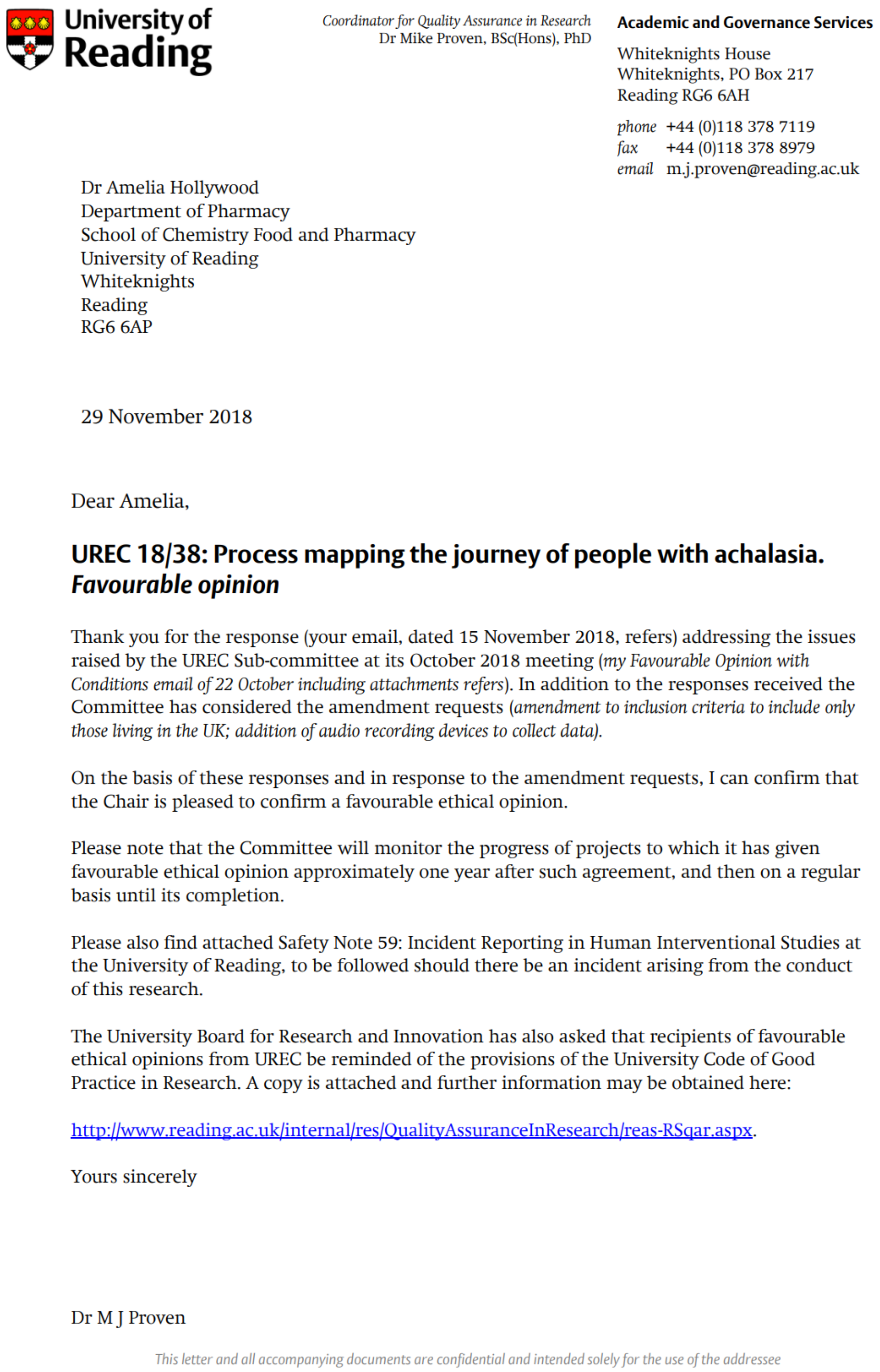
Appendix 1: Study 1-Ethics approval UREC Ref 18/38



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29 November 2018

Dear Amelia,

UREC 18/38: Process mapping the journey of people with achalasia.
Favourable opinion

Thank you for the response (your email, dated 15 November 2018, refers) addressing the issues raised by the UREC Sub-committee at its October 2018 meeting (*my Favourable Opinion with Conditions email of 22 October including attachments refers*). In addition to the responses received the Committee has considered the amendment requests (*amendment to inclusion criteria to include only those living in the UK; addition of audio recording devices to collect data).*

On the basis of these responses and in response to the amendment requests, I can confirm that the Chair is pleased to confirm a favourable ethical opinion.

Please note that the Committee will monitor the progress of projects to which it has given favourable ethical opinion approximately one year after such agreement, and then on a regular basis until its completion.

Please also find attached Safety Note 59: Incident Reporting in Human Interventional Studies at the University of Reading, to be followed should there be an incident arising from the conduct of this research.

The University Board for Research and Innovation has also asked that recipients of favourable ethical opinions from UREC be reminded of the provisions of the University Code of Good Practice in Research. A copy is attached and further information may be obtained here:

http://www.reading.ac.uk/internal/res/QualityAssuranceInResearch/reas-RSqar.aspx.

Yours sincerely

Dr M J Proven

Coordinator for Quality Assurance in Research (UREC Secretary)
cc: Dr John Wright (Chair); Dr Rosemary Lim (Researcher); Melika Kalantari (PhD Student);

Appendix 2: Study 1- Structure of the mapping sessions

Process Map Workshop Guide

Introduction: (Researcher allows 10 minutes to introduce herself, her study, and to go over the ground rules of the session)

Welcome
I am Melika Kalantari PhD researcher from Reading School of Pharmacy, University of Reading. I hope to explore your journey with achalasia and to learn from the experiences you share about your journey from diagnosis to treatment.

Thank you for taking part in this research. The aim of this workshop is to explore your journey step by step from the very beginning, and gain some in depth insight into the processes which were involved in your journey.

Ground Rules

Before we start, I would like to mention a few things about this meeting.

To maintain confidentiality, I would like to emphasise that all participants must keep the information provided in this session confidential. Please do not discuss or share the information with others beyond this group.

I, as the researcher, will also make sure that all identifiable information (names, email and/or telephone numbers, video recordings and demographic details) is handled with care and stored securely in order to maintain confidentiality throughout this research.

In order to get the most out of this session, I would like to ask you to contribute to the session effectively. This means encouraging openness, constructive feedback, listening, observing confidentiality and showing respect.

I would appreciate if you could

1. Put your phones on silent.
2. Observe the courtesy of one person speaking at a time.

If you have any concerns or comments during the session please share them with me and please avoid having conversations on the side.

This session is being video recorded for accuracy checking purposes only.

Before diagnosis (Researcher allows 20 minutes to ask participants questions about their respective journeys before they were given a diagnosis)

Using sequential flow diagram
A scenario is used that helps participants describe a sequence of events that occurs during one particular execution of a system.

SCENARIO: I want you to go back to when you first started getting the symptoms and recall what you did when you first experienced those symptoms.
Participants describe the flow of events and actions.
Prompts:
What happened?
How long after you experienced the symptoms did you go to see the GP?
Tell me what you remember about your appointment with your GP?
What happened after you saw your GP?
How long after you visited the GP were you referred to a consultant?

Diagnosis (Researcher allows 20 minutes to ask participants questions about their respective journeys while they were in the lead-up to, and process of, receiving diagnosis)

Could you explain in detail the steps you took in order to get a diagnosis?
Who did you see at the hospital?
What tests were you offered in order to get a diagnosis?
Who gave you the final diagnosis and how?
What happened after you got a name for your symptoms?

After Diagnosis (Researcher allows 20 minutes to ask participants questions about their respective journeys after diagnosis.)

What treatments have you been offered?
What was the process of choosing a treatment?
Who helped you to make an appropriate decision?

Conclusion (10 minutes)

Is there anything else you would like to add to any steps of this process map?
Are there any questions you would like to ask me?

That concludes our mapping session. Thank you so much for coming and sharing your experiences, perceptions and journeys with me.

Appendix 3: Study 1-Demographic questionnaire

1. Are you: ☐ Male ☐ Female ☐Other ☐ Prefer not to say

2. How old are you? ___________ (years)

3. Which of the following best describes you:

☐ Black ☐ Asian ☐ White ☐ Other: Specify _____________

4. Are you:

☐ Living alone or ☐ Living with a partner/family/friends

5. Do you work?

Full time ☐ Part time ☐ Retired ☐

I am a full time parent/carer ☐ I am not working at the moment ☐

6. How long have you been diagnosed with achalasia? ___________

7. Have you ever had any of these medical interventions for achalasia? If yes please tick all that apply.

Botox ☐ Balloon dilatation ☐ Heller myotomy ☐
Peroral Endoscopic Myotomy (POEM) ☐
Other ☐ Specify: ___________

Appendix 4: Study 2- Ethics approval SREC Ref 40/2020

31/07/2023, 12:24 Email - Melika Kalantari - Outlook

SREC Approval - Study Number 40/2020

Julie Lovegrove <j.a.lovegrove@reading.ac.uk>
Wed 21/10/2020 13:51
To:Rosemary Lim <r.h.m.lim@reading.ac.uk>;Amelia Hollywood <a.hollywood@reading.ac.uk>;Melika Kalantari <melika.kalantari@pgr.reading.ac.uk>; [redacted]

Cc:Barbara Parr <b.l.parr@reading.ac.uk>

1 attachments (3 MB)
40.2020 SREC.docx;

Dear Amelia, Rosemary, Melika and Majid

I am pleased to inform you that Dr Kat Bicknell has given a favourable opinion for conduct for your study, 'Co-designing an intervention to change eating behaviour in people living with achalasia' via the in-School exceptions route. This email constitutes your permission to proceed with the studies as described in your application. The following study number has been assigned to your study and you should quote this number in any correspondence you undertake about your studies.

STUDY Number – 40/2020

If you feel that you need to make changes to the way your studies are run, please let us know at the earliest opportunity and we can advise you of whether a formal amendment to your proposal is required or not.

I wish you the best of luck with the projects and finish by reminding you of the need for safe custody of project data at all times (a service that Barbara Parr, copied in, can provide if you require it).

Kind regards

Professor Julie Lovegrove

SCFP Research Ethics Chair

https://outlook.office.com/mail/id/AAQkADVmYjYyZjY5LWYzN2YtNGVlOC1hYWZkLWQ1NmNiYWMxZTA1MwAQACiLVZeijKpBrzWf8d8Gny4%3… 1/1

Appendix 5: Study 2- Focus group topic guide

Thank you so much for your time and taking part in this group discussion today. My name is Melika Kalantari and I am a PhD researcher exploring different eating behaviours with achalasia and co-designing an intervention for the long-term management of achalasia. My current research is focused around co-designing an intervention with people living with achalasia in order to address one of the many challenges that you face on a daily basis.

What I want to discuss today are the ways an eating behaviour can be changed in order to facilitate symptoms management. As part of this first of all I want you to prioritise the eating behaviours that I will present to you before we start co-designing an intervention. Does that make sense?

Any question about the information sheet?

I should have all the consent forms and demographic questions by this point.

I should check people's set-ups and check that they are ok to participate in the focus group without getting disturbed. I should also check that they are alone. And they are comfortable in using the application and they do not have any technical issues.

At the beginning of each focus group the ground rules such as speaking one at a time and not interrupting other people will be stated.

Before I start, we have a few ground rules for how the virtual focus group will run.

1. Respect the opinions of others in the group. There are no right or wrong answers, we are just exploring this topic and are really interested in hearing about all of your opinions.
2. It's important to let everyone to have their say. If you feel you have been talking too much take a step down and let others speak, and vice versa, if you have not said much, don't be afraid to step up and have your say.
3. Listen to each other and talk to each other.
4. Confidentiality- please respect the privacy of others in the group, and anything that is discussed within the groups, should remain in the group. Please don't talk about anything outside of our discussion today.

Just so you know what is coming up, first I will present some eating behaviours that emerged from our previous research study. I want you to talk about them and decide what are the eating behaviours that you all find challenging and would like to change in the long run. We will then move onto different ways to change behaviour and try to co-design an intervention putting some eating behaviours the centre of that co-design. I will give you a couple of examples around the presented topic and I hope that everyone will feel comfortable in taking part and sharing their thoughts.

Do you have any questions before we start?

Start the recording

Can everyone introduce themselves?

First virtual focus group

In session one the facilitator will discuss and present a list of eating behaviours that emerged from previous research. The researcher will present a list of effective BCTs that were found to be effective in changing behaviour in other conditions and she will ask the participants to discuss them based on their experiences with achalasia. A list of eating behaviour will also be prepared and presented to the participants so they can prioritise those eating behaviours in the order of the most challenging to the least and also discuss the potential eating behaviours that needs an intervention. They will then be asked to co-design an intervention based on the chosen eating behaviour and the BCTs that will be presented to them. They will also be presented with the behaviour change wheel and the COM-B model. They will then be asked to discuss what resonates to them the most for designing an intervention for a specific eating behaviour choosing from the different taxonomies that have been shown to be effective in changing eating behaviours.

Second virtual focus group

In our first virtual focus group people were gathered to prioritise an eating behaviour that the majority found challenging and then they tried to co-design an intervention to tackle that eating behaviour. The aim of the second focus group is to present the co-designed intervention and ask them if what was designed in the first session resonate with people in the second virtual focus group and also discuss how they want that intervention to be delivered. Different BCTs and behaviour change activities can be delivered differently therefore it is important to discuss and find out how that intervention could be delivered so people could get the most of it. They can decide and discuss to have a face-to-face meeting to deliver that intervention or they might prefer to have an online forum or a mobile app.

Third virtual focus group

In the last virtual focus group people will be presented with the selected eating behaviour and the co-designed intervention from the first virtual focus group followed by the chosen delivery method in the second virtual focus group in order to verify the completed co-designed intervention. Participants will be asked to discuss the co-designed intervention to see whether the co-designed intervention resonate with them and whether it will be helpful for them and amend it if needed.

Appendix 6: Study 2- Demographic Questionnaire

Demographic Questionnaire

0%

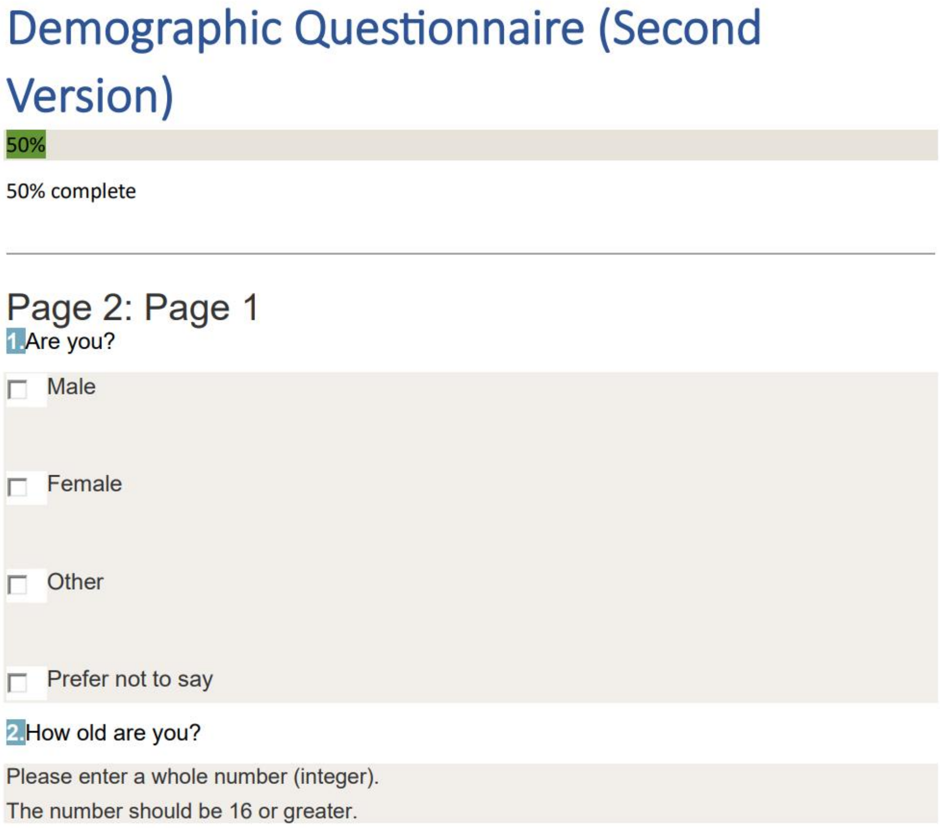
0% complete

Page 1: Co-designing an intervention to change eating behaviour in people living with achalasia

Thank you so much for agreeing to take part in our study.

Please answer the following questions.

Approval number: 40/2020; Version 2: 16/09/2020



Demographic Questionnaire (Second Version)

50%

50% complete

Page 2: Page 1

1. Are you?

☐ Male

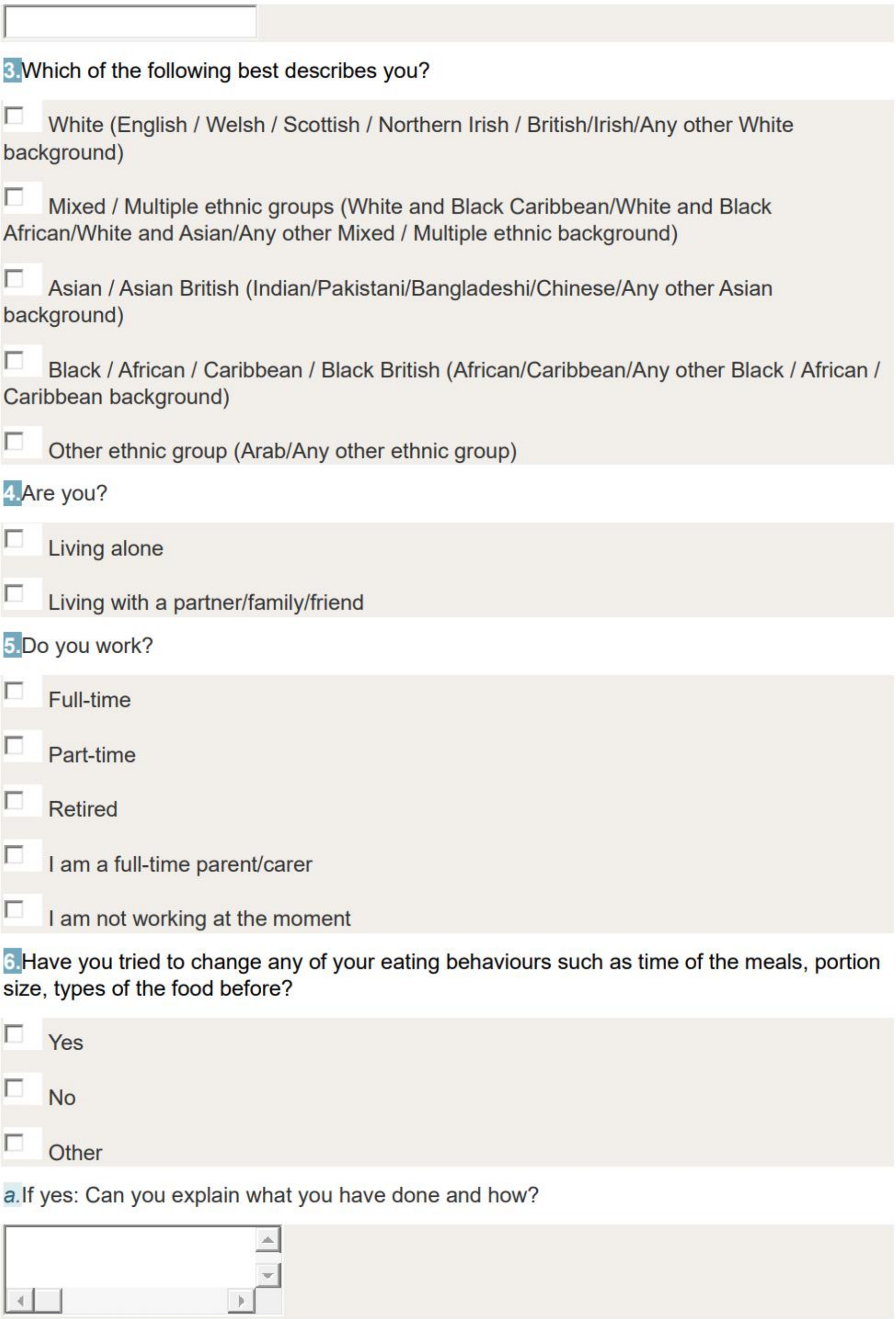
☐ Female

☐ Other

☐ Prefer not to say

2. How old are you?

Please enter a whole number (integer).
The number should be 16 or greater.



3. Which of the following best describes you?

☐ White (English / Welsh / Scottish / Northern Irish / British/Irish/Any other White background)

☐ Mixed / Multiple ethnic groups (White and Black Caribbean/White and Black African/White and Asian/Any other Mixed / Multiple ethnic background)

☐ Asian / Asian British (Indian/Pakistani/Bangladeshi/Chinese/Any other Asian background)

☐ Black / African / Caribbean / Black British (African/Caribbean/Any other Black / African / Caribbean background)

☐ Other ethnic group (Arab/Any other ethnic group)

4. Are you?

☐ Living alone

☐ Living with a partner/family/friend

5. Do you work?

☐ Full-time

☐ Part-time

☐ Retired

☐ I am a full-time parent/carer

☐ I am not working at the moment

6. Have you tried to change any of your eating behaviours such as time of the meals, portion size, types of the food before?

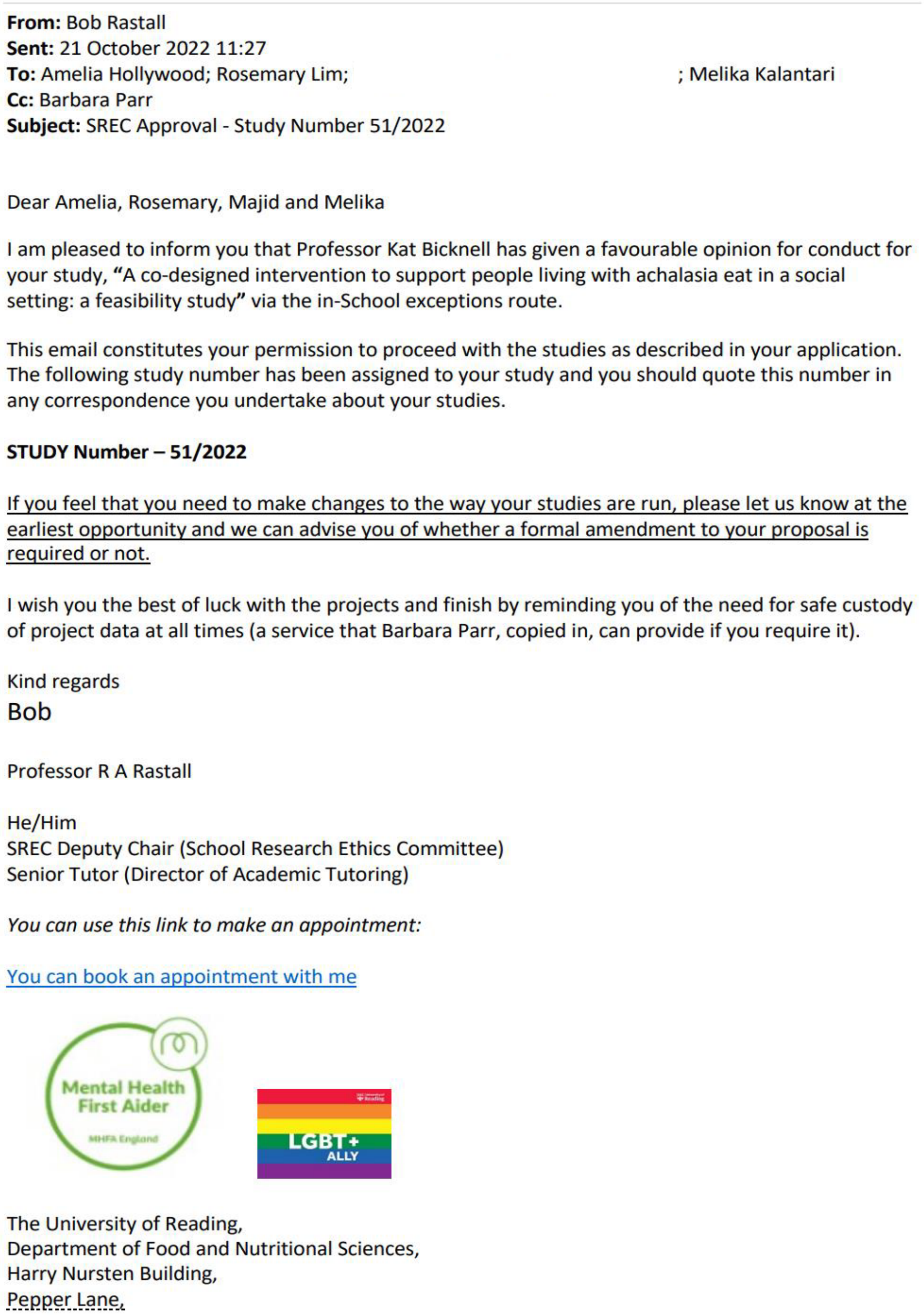
☐ Yes

☐ No

☐ Other

a. If yes: Can you explain what you have done and how?

Appendix 7: Study 3-Ethics approval SREC Ref 51/2022



From: Bob Rastall
Sent: 21 October 2022 11:27
To: Amelia Hollywood; Rosemary Lim; ; Melika Kalantari
Cc: Barbara Parr
Subject: SREC Approval - Study Number 51/2022

Dear Amelia, Rosemary, Majid and Melika

I am pleased to inform you that Professor Kat Bicknell has given a favourable opinion for conduct for your study, **"**A co-designed intervention to support people living with achalasia eat in a social setting: a feasibility study**"** via the in-School exceptions route.

This email constitutes your permission to proceed with the studies as described in your application. The following study number has been assigned to your study and you should quote this number in any correspondence you undertake about your studies.

STUDY Number – 51/2022

If you feel that you need to make changes to the way your studies are run, please let us know at the earliest opportunity and we can advise you of whether a formal amendment to your proposal is required or not.

I wish you the best of luck with the projects and finish by reminding you of the need for safe custody of project data at all times (a service that Barbara Parr, copied in, can provide if you require it).

Kind regards
Bob

Professor R A Rastall

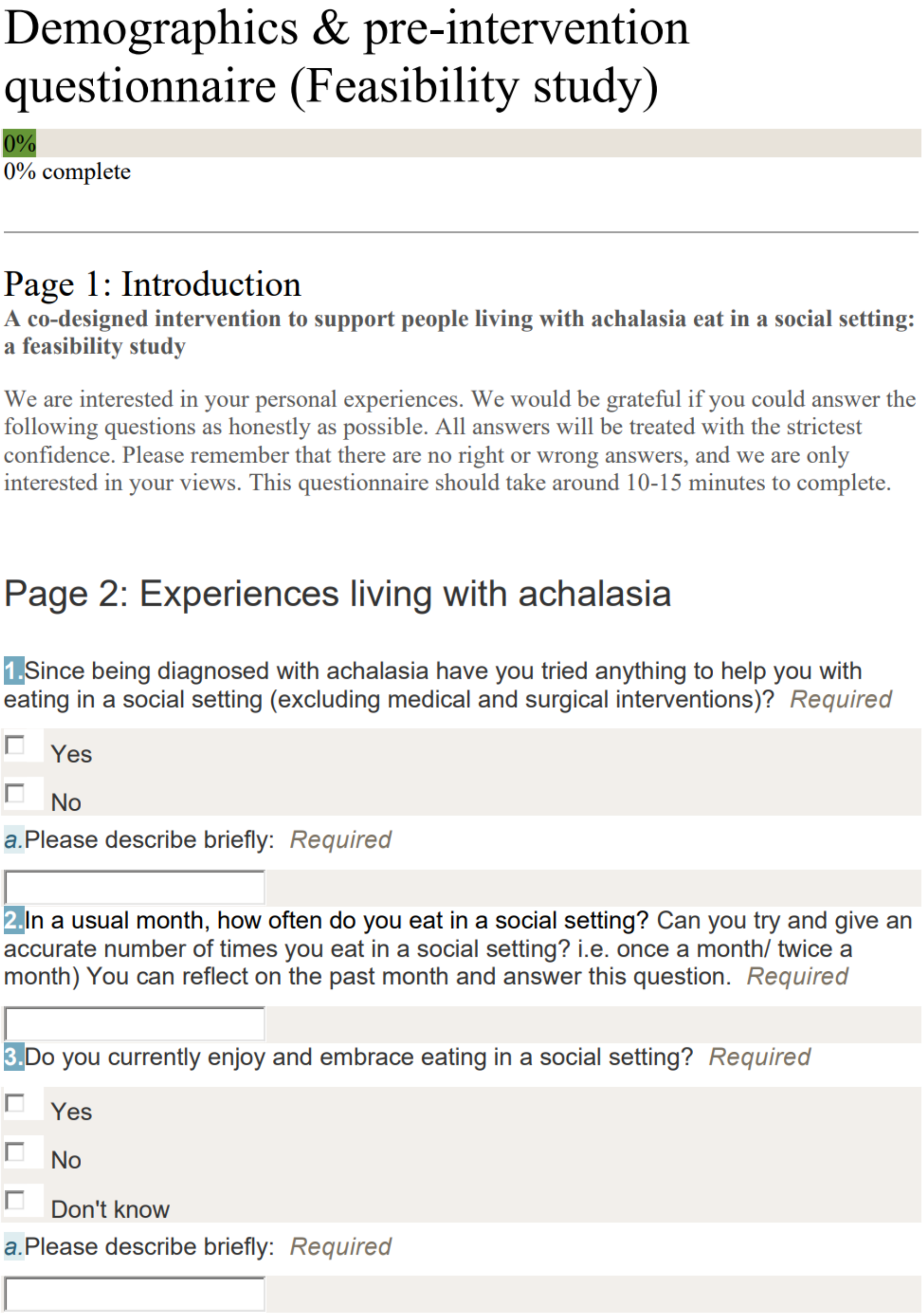
He/Him
SREC Deputy Chair (School Research Ethics Committee)
Senior Tutor (Director of Academic Tutoring)

You can use this link to make an appointment:

You can book an appointment with me

The University of Reading,
Department of Food and Nutritional Sciences,
Harry Nursten Building,
Pepper Lane,

Appendix 8: Study 3-Demographics and Pre-intervention questionnaire



Demographics & pre-intervention questionnaire (Feasibility study)

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Page 1: Introduction

A co-designed intervention to support people living with achalasia eat in a social setting: a feasibility study

We are interested in your personal experiences. We would be grateful if you could answer the following questions as honestly as possible. All answers will be treated with the strictest confidence. Please remember that there are no right or wrong answers, and we are only interested in your views. This questionnaire should take around 10-15 minutes to complete.

Page 2: Experiences living with achalasia

1. Since being diagnosed with achalasia have you tried anything to help you with eating in a social setting (excluding medical and surgical interventions)? *Required*

☐ Yes

☐ No

a. Please describe briefly: *Required*

2. In a usual month, how often do you eat in a social setting? Can you try and give an accurate number of times you eat in a social setting? i.e. once a month/ twice a month) You can reflect on the past month and answer this question. *Required*

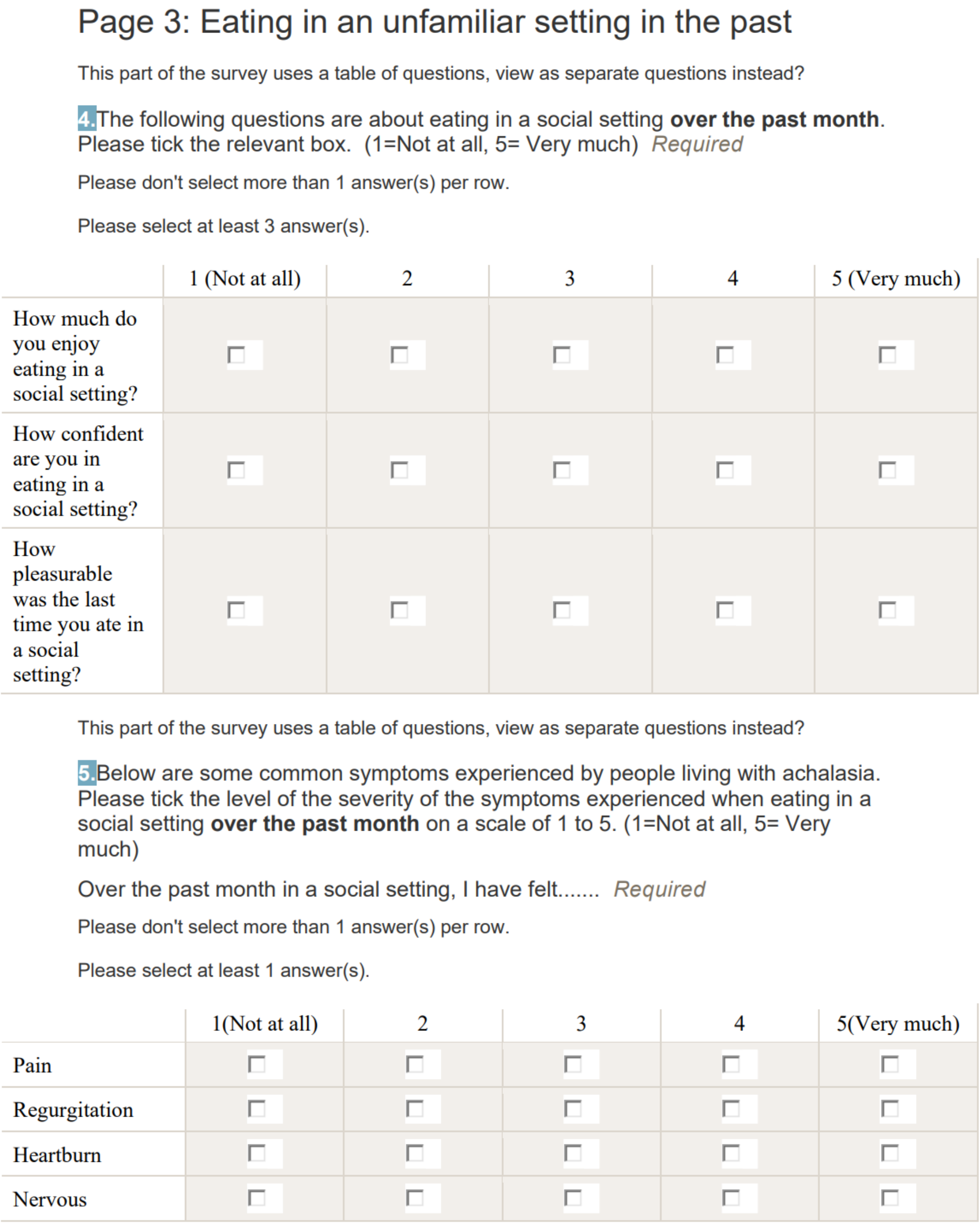
3. Do you currently enjoy and embrace eating in a social setting? *Required*

☐ Yes

☐ No

☐ Don't know

a. Please describe briefly: *Required*



Page 3: Eating in an unfamiliar setting in the past

This part of the survey uses a table of questions, view as separate questions instead?

4.The following questions are about eating in a social setting **over the past month**. Please tick the relevant box. (1=Not at all, 5= Very much) *Required*

Please don't select more than 1 answer(s) per row.

Please select at least 3 answer(s).

	1 (Not at all)	2	3	4	5 (Very much)
How much do you enjoy eating in a social setting?	☐	☐	☐	☐	☐
How confident are you in eating in a social setting?	☐	☐	☐	☐	☐
How pleasurable was the last time you ate in a social setting?	☐	☐	☐	☐	☐

This part of the survey uses a table of questions, view as separate questions instead?

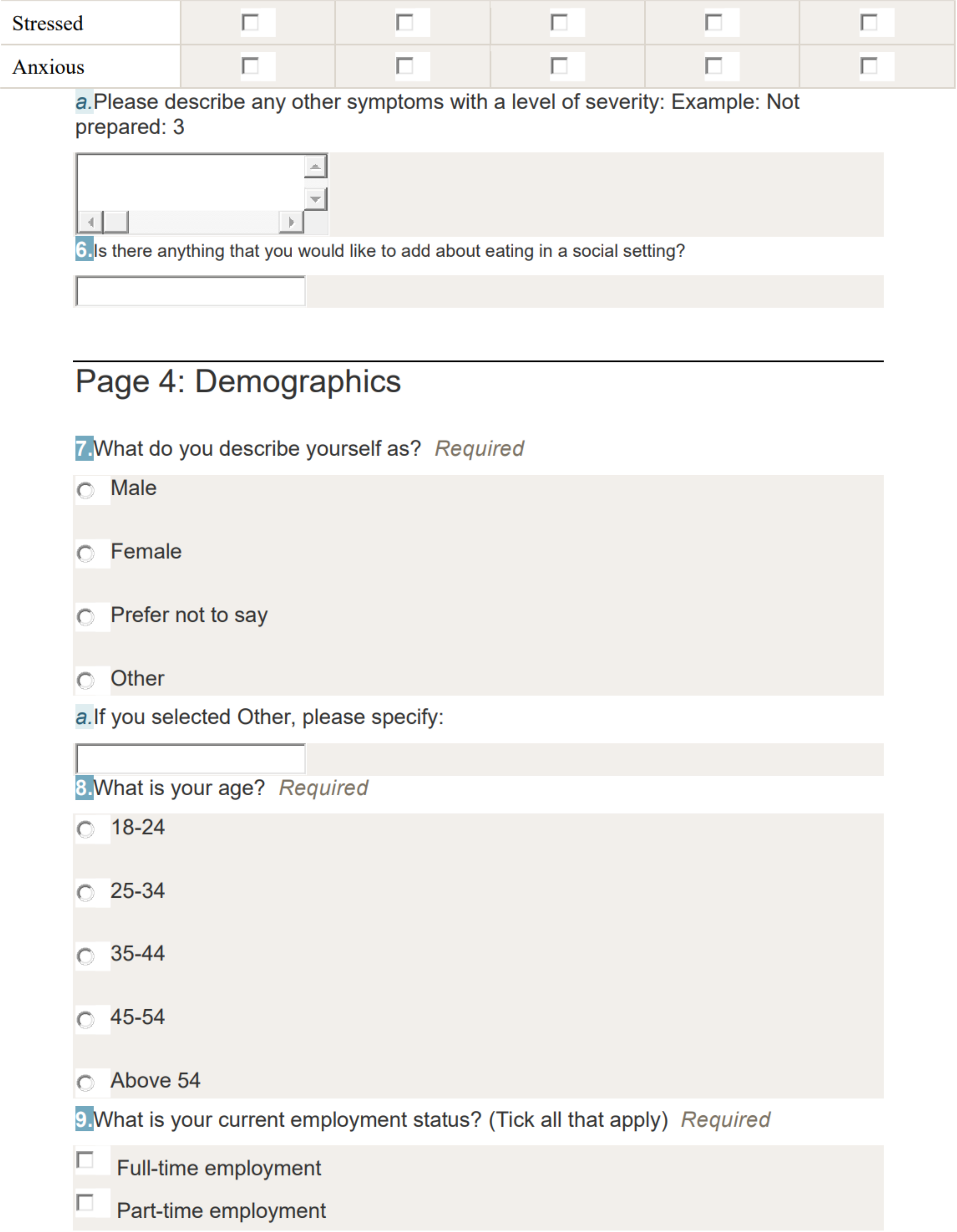
5.Below are some common symptoms experienced by people living with achalasia. Please tick the level of the severity of the symptoms experienced when eating in a social setting **over the past month** on a scale of 1 to 5. (1=Not at all, 5= Very much)

Over the past month in a social setting, I have felt....... *Required*

Please don't select more than 1 answer(s) per row.

Please select at least 1 answer(s).

	1(Not at all)	2	3	4	5(Very much)
Pain	☐	☐	☐	☐	☐
Regurgitation	☐	☐	☐	☐	☐
Heartburn	☐	☐	☐	☐	☐
Nervous	☐	☐	☐	☐	☐



Stressed	☐	☐	☐	☐	☐
Anxious	☐	☐	☐	☐	☐

a. Please describe any other symptoms with a level of severity: Example: Not prepared: 3

6. Is there anything that you would like to add about eating in a social setting?

Page 4: Demographics

7. What do you describe yourself as? *Required*

○ Male

○ Female

○ Prefer not to say

○ Other

a. If you selected Other, please specify:

8. What is your age? *Required*

○ 18-24

○ 25-34

○ 35-44

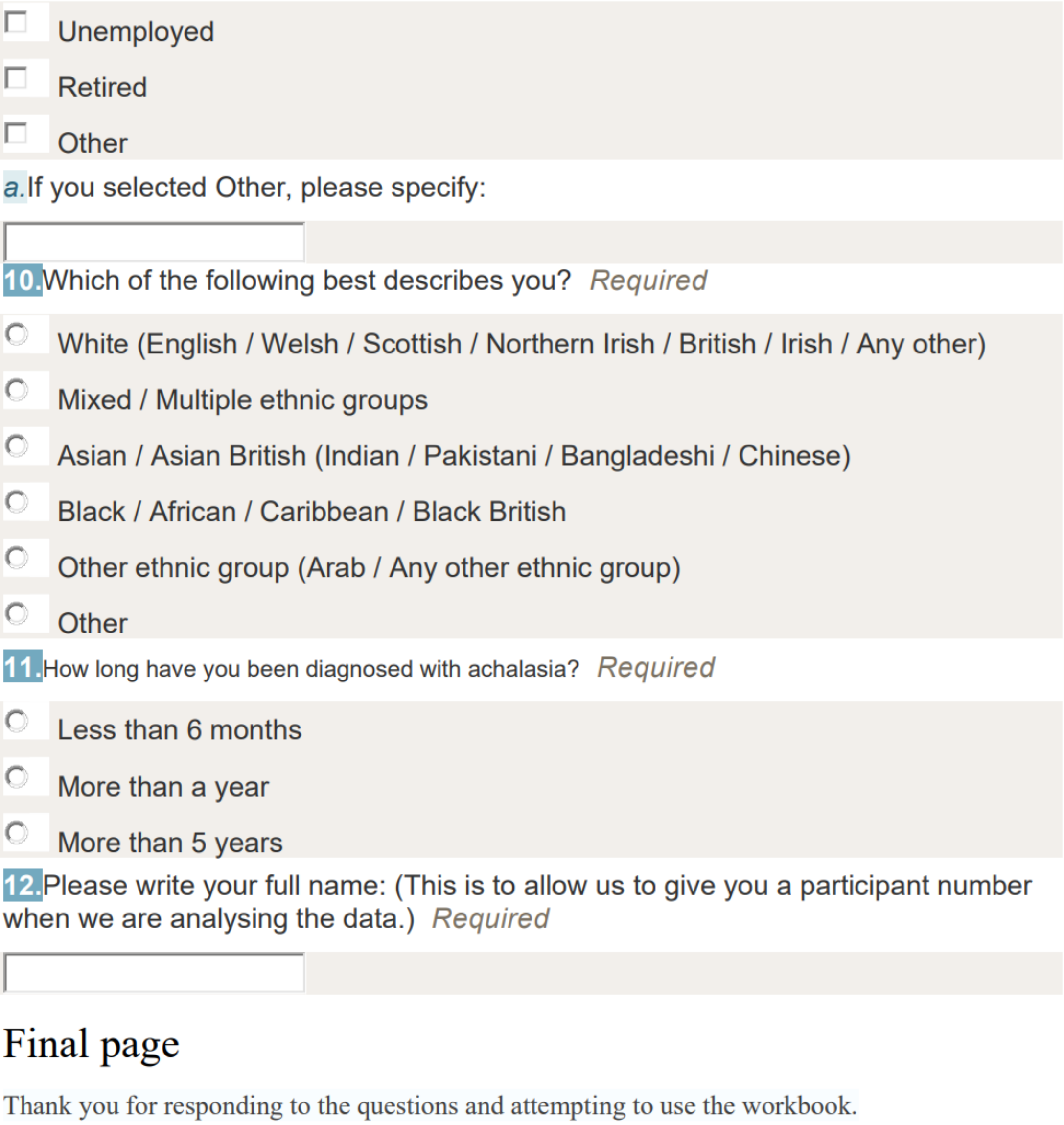
○ 45-54

○ Above 54

9. What is your current employment status? (Tick all that apply) *Required*

☐ Full-time employment

☐ Part-time employment



☐ Unemployed

☐ Retired

☐ Other

a. If you selected Other, please specify:

☐

10. Which of the following best describes you? *Required*

○ White (English / Welsh / Scottish / Northern Irish / British / Irish / Any other)

○ Mixed / Multiple ethnic groups

○ Asian / Asian British (Indian / Pakistani / Bangladeshi / Chinese)

○ Black / African / Caribbean / Black British

○ Other ethnic group (Arab / Any other ethnic group)

○ Other

11. How long have you been diagnosed with achalasia? *Required*

○ Less than 6 months

○ More than a year

○ More than 5 years

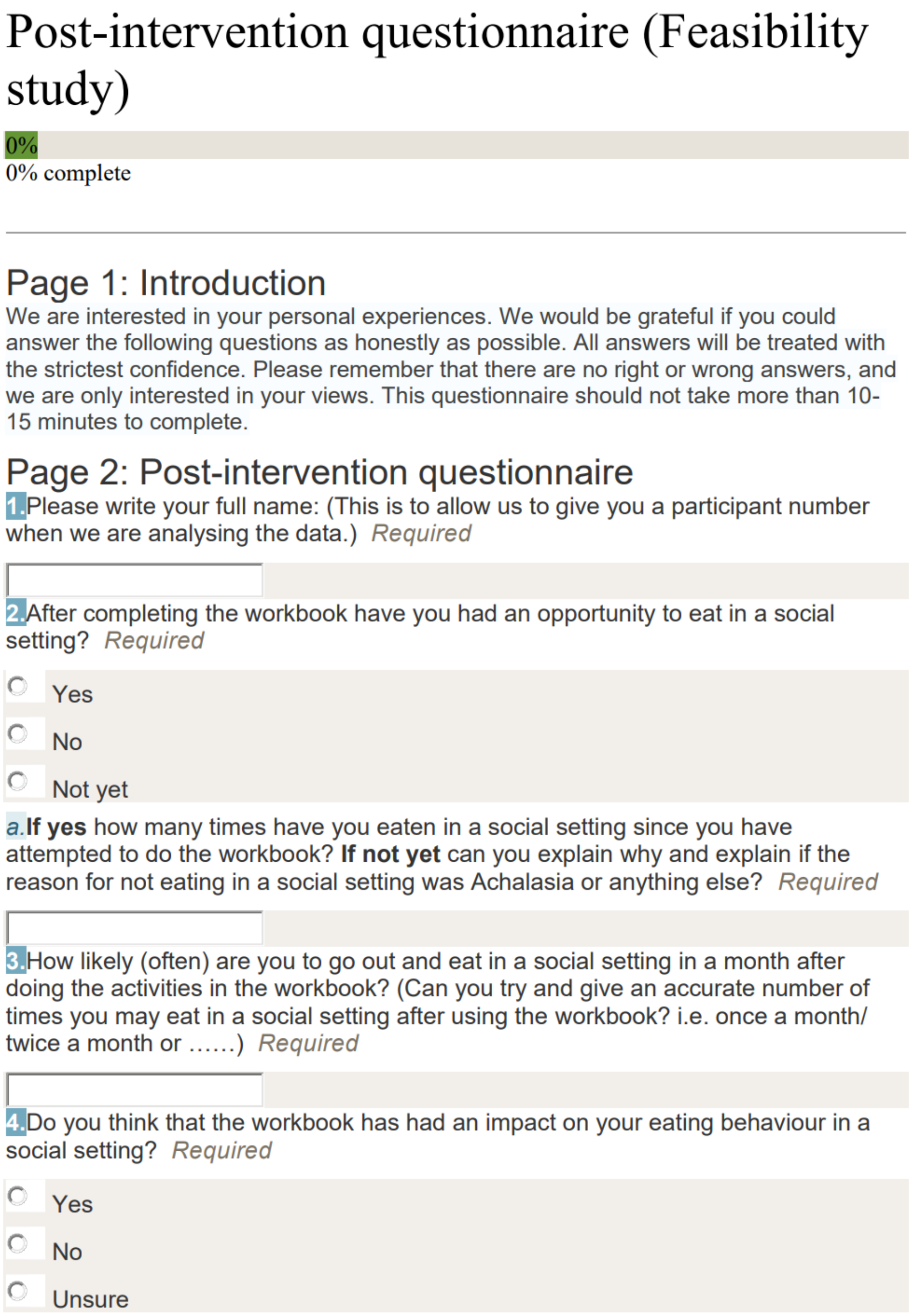
12. Please write your full name: (This is to allow us to give you a participant number when we are analysing the data.) *Required*

☐

Final page

Thank you for responding to the questions and attempting to use the workbook.

Appendix 9: Study 3- Post-intervention questionnaire



Post-intervention questionnaire (Feasibility study)

0%

0% complete

Page 1: Introduction

We are interested in your personal experiences. We would be grateful if you could answer the following questions as honestly as possible. All answers will be treated with the strictest confidence. Please remember that there are no right or wrong answers, and we are only interested in your views. This questionnaire should not take more than 10-15 minutes to complete.

Page 2: Post-intervention questionnaire

1. Please write your full name: (This is to allow us to give you a participant number when we are analysing the data.) *Required*

2. After completing the workbook have you had an opportunity to eat in a social setting? *Required*

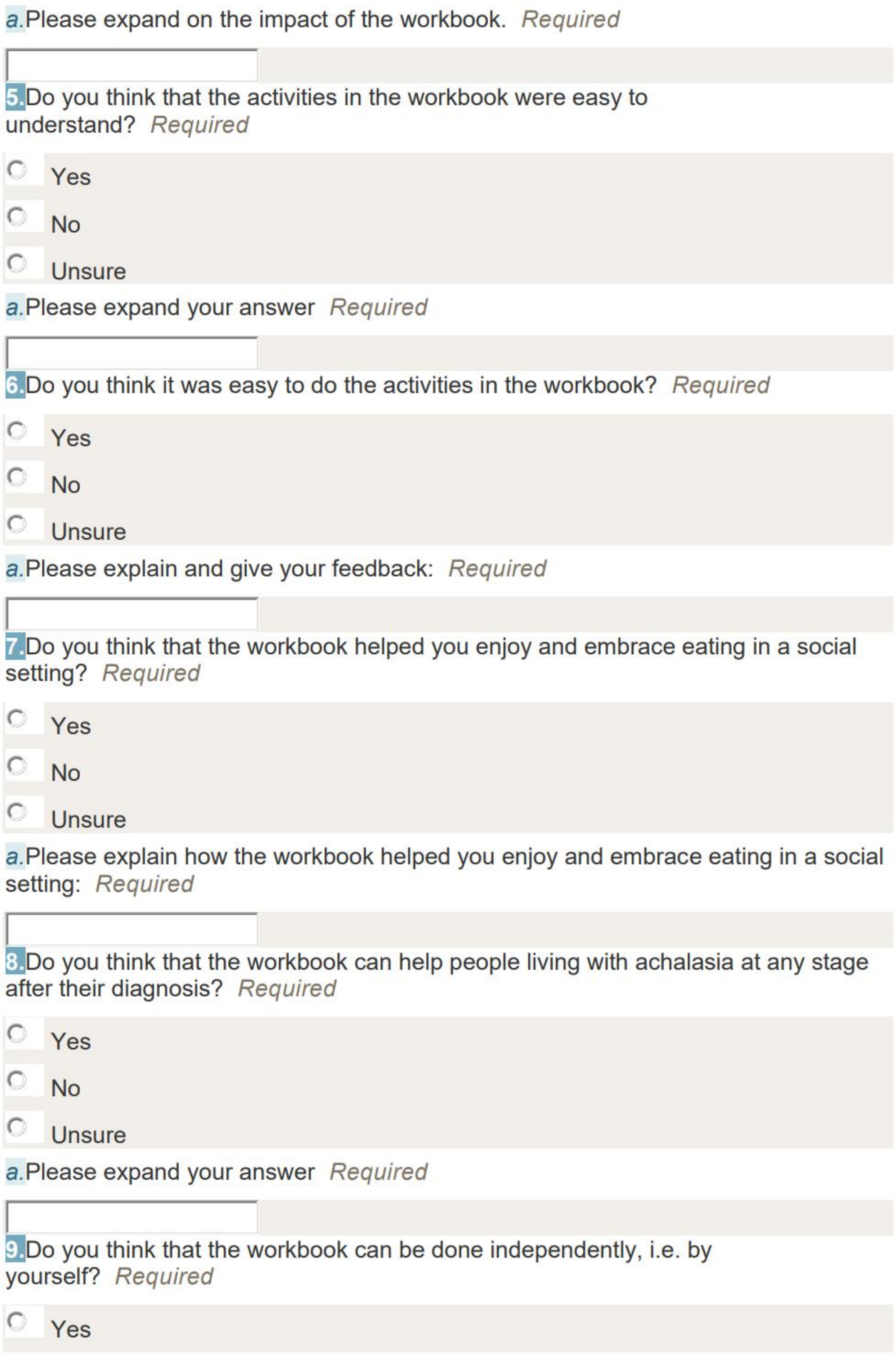
○ Yes
○ No
○ Not yet

a. **If yes** how many times have you eaten in a social setting since you have attempted to do the workbook? **If not yet** can you explain why and explain if the reason for not eating in a social setting was Achalasia or anything else? *Required*

3. How likely (often) are you to go out and eat in a social setting in a month after doing the activities in the workbook? (Can you try and give an accurate number of times you may eat in a social setting after using the workbook? i.e. once a month/ twice a month or ……) *Required*

4. Do you think that the workbook has had an impact on your eating behaviour in a social setting? *Required*

○ Yes
○ No
○ Unsure



a. Please expand on the impact of the workbook. *Required*

5. Do you think that the activities in the workbook were easy to understand? *Required*

○ Yes
○ No
○ Unsure

a. Please expand your answer *Required*

6. Do you think it was easy to do the activities in the workbook? *Required*

○ Yes
○ No
○ Unsure

a. Please explain and give your feedback: *Required*

7. Do you think that the workbook helped you enjoy and embrace eating in a social setting? *Required*

○ Yes
○ No
○ Unsure

a. Please explain how the workbook helped you enjoy and embrace eating in a social setting: *Required*

8. Do you think that the workbook can help people living with achalasia at any stage after their diagnosis? *Required*

○ Yes
○ No
○ Unsure

a. Please expand your answer *Required*

9. Do you think that the workbook can be done independently, i.e. by yourself? *Required*

○ Yes

○ No

a. Please expand your answer *Required*

☐

This part of the survey uses a table of questions, view as separate questions instead?

10. The following questions are about eating in a social setting after using the activities in the workbook. Please tick the relevant number. *Required*

Please don't select more than 1 answer(s) per row.

	1 (not at all)	2	3	4	5 (very much)
How confident are you in eating in a social setting?	☐	☐	☐	☐	☐
How much do you enjoy eating in a social setting?	☐	☐	☐	☐	☐
How pleasurable was the last time you ate in a social setting?	☐	☐	☐	☐	☐

Please select at least 1 answer(s).

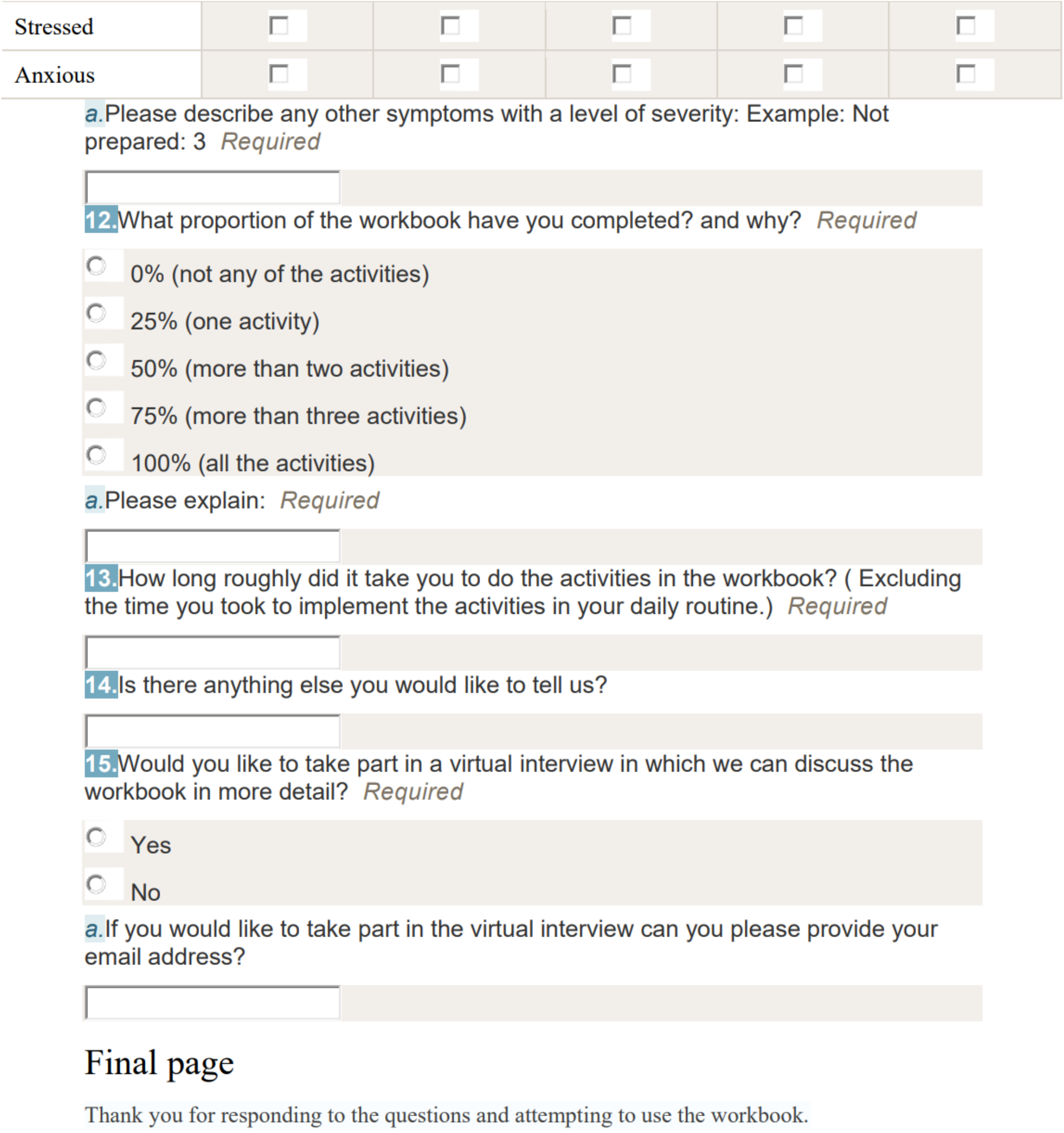
This part of the survey uses a table of questions, view as separate questions instead?

11. Below are some common symptoms experienced by people living with achalasia. Please tick the level of the severity of the symptoms experienced when eating in a social setting after using the activities in the workbook. *Required*

Please don't select more than 1 answer(s) per row.

Please select at least 1 answer(s).

	1 (not at all)	2	3	4	5 (very much)
Pain	☐	☐	☐	☐	☐
Regurgitation	☐	☐	☐	☐	☐
Heartburn	☐	☐	☐	☐	☐
Nervous	☐	☐	☐	☐	☐



Stressed	☐	☐	☐	☐	☐
Anxious	☐	☐	☐	☐	☐

a. Please describe any other symptoms with a level of severity: Example: Not prepared: 3 *Required*

☐

12. What proportion of the workbook have you completed? and why? *Required*

○ 0% (not any of the activities)
○ 25% (one activity)
○ 50% (more than two activities)
○ 75% (more than three activities)
○ 100% (all the activities)

a. Please explain: *Required*

☐

13. How long roughly did it take you to do the activities in the workbook? (Excluding the time you took to implement the activities in your daily routine.) *Required*

☐

14. Is there anything else you would like to tell us?

☐

15. Would you like to take part in a virtual interview in which we can discuss the workbook in more detail? *Required*

○ Yes
○ No

a. If you would like to take part in the virtual interview can you please provide your email address?

☐

Final page

Thank you for responding to the questions and attempting to use the workbook.

Appendix 10: Study 3 - Semi-structured interview guide

Interview schedule:

- What do you think of this workbook? What are your general feedback on it?
- What do you think of the activities in the workbook? (Prompts: were they easy to implement, were they easy to understand? Can you explain how?
- What do you think of the layout and the format of the workbook?
- If the activities are not easy to do or not achievable, how would you change the tasks or activities in the workbook so it is easier to do?
- Can you tell me what you liked the most about the workbook?
- Can you tell me what you liked the least about the workbook?
- Do you think the workbook is a handy tool for you for future use?
- In terms of the usability of the workbook do you think that the workbook is something that you will reflect on next time you want to eat in a social setting?
- In your opinion what was the most useful activity in the workbook?
- In your opinion, do you think this workbook is an acceptable intervention to help people living with achalasia to eat more comfortably in social settings?
- In your opinion, do you think that the workbook is a practical tool to use before going to eat in a social setting or preparing for future events?
- Based on your experience after using the workbook, do you think the activities in the workbook were effective (did it change your perception) in changing your eating behaviour for eating in a social setting?
- In your opinion, what are the pros and cons of using this intervention to support your eating behaviours in a social setting?
-

Capability:

Did the activities help to develop skills and improve your ability and to eat in a social setting? Can you tell me in what ways?

Opportunity:

Did the activities in the workbook help you reduce the negative emotions that you might have had about eating in a social setting? How did it do that?

Motivation:

In what way does the workbook help you eat in a social setting? (Prompts: confidence, motivation, more relaxed in the social situation)

How do you perceive that this workbook could impact eating in a social setting for you?

Other questions:

How did you find the workbook as a whole?

Do you have any specific feedback on any specific section of the workbook?

Appendix 11: Co-designed intervention

Living with achalasia:

Embrace and enjoy eating in a social setting

Tips and activities to help those living with achalasia eat in a social setting

A workbook co-designed by researchers and people living with Achalasia.

Who are we?

Melika Kalantari – PhD Student and Pharmacist. Interest in supporting people living with Achalasia.

Amelia Hollywood – Lecturer in Health Services Research and Health Psychologist. Interest in supporting people living with chronic conditions.

Rosemary Lim – Associate Professor in Medication Use and Safety and Pharmacist. Interest in co-designing research.

Majid Hashemi – Upper GI Surgeon. Interest in the treatment of Achalasia.

Achalasia Action – support group for people living with Achalasia. Supports research into Achalasia.

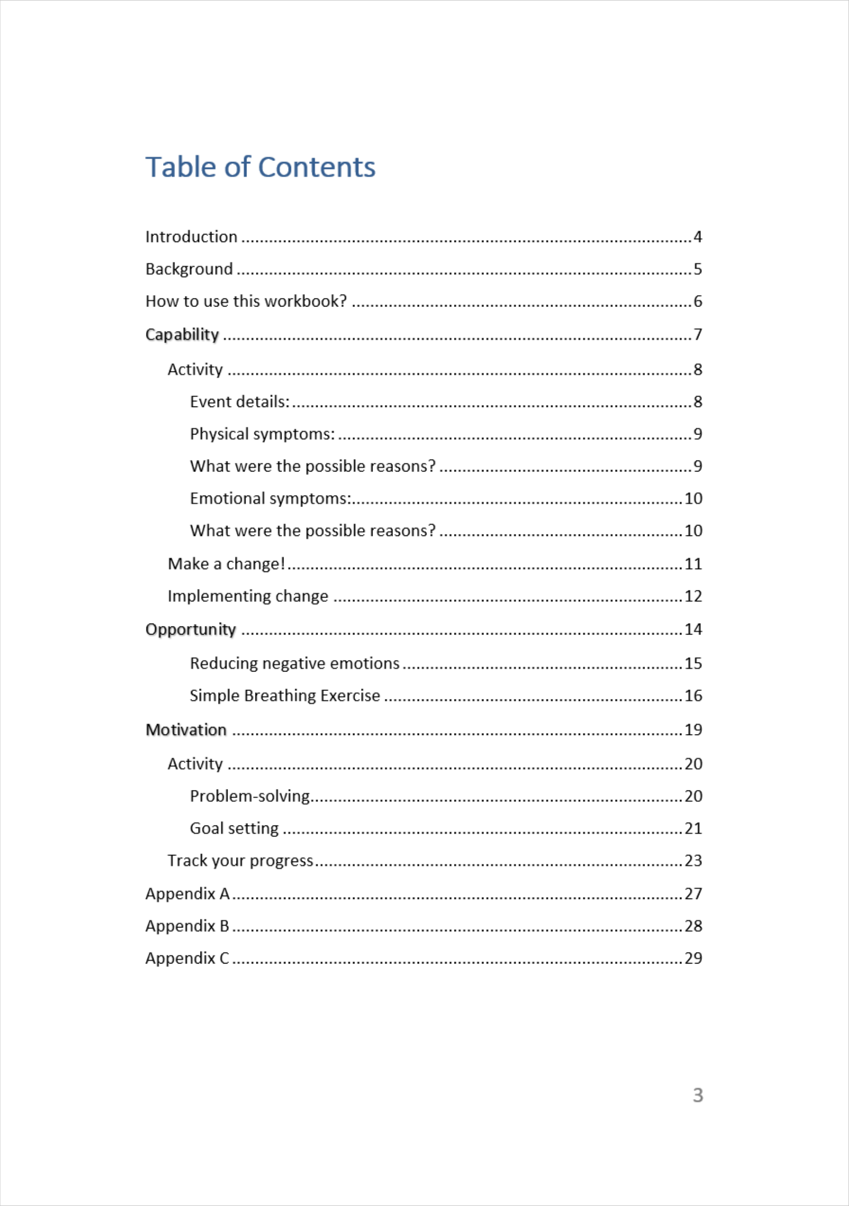
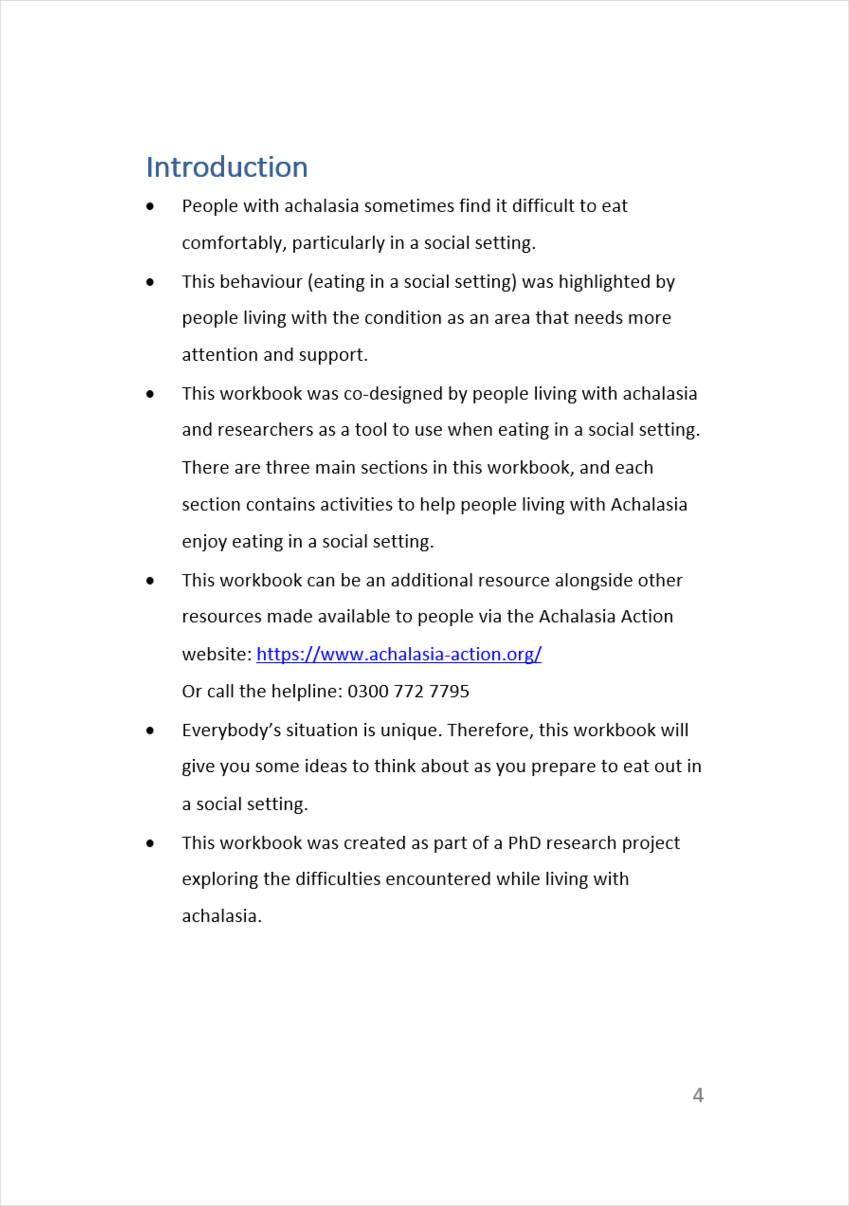


Table of Contents



Introduction

- People with achalasia sometimes find it difficult to eat comfortably, particularly in a social setting.
- This behaviour (eating in a social setting) was highlighted by people living with the condition as an area that needs more attention and support.
- This workbook was co-designed by people living with achalasia and researchers as a tool to use when eating in a social setting. There are three main sections in this workbook, and each section contains activities to help people living with Achalasia enjoy eating in a social setting.
- This workbook can be an additional resource alongside other resources made available to people via the Achalasia Action website: https://www.achalasia-action.org/
  Or call the helpline: 0300 772 7795
- Everybody's situation is unique. Therefore, this workbook will give you some ideas to think about as you prepare to eat out in a social setting.
- This workbook was created as part of a PhD research project exploring the difficulties encountered while living with achalasia.

Background

The workbook is designed using scientific evidence using the COM-B model (Figure 1). This workbook is not a one size fit all. We appreciate that everyone's symptoms and experiences can be different. This is the model we used with people living with achalasia to create this workbook. The activities in this workbook were co-designed using the three key elements of this model. You can use this model to provide your own personalised approach.

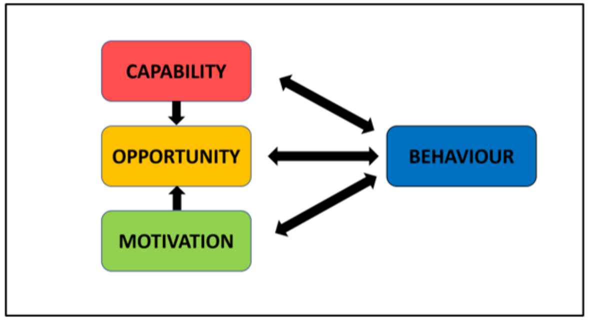


Figure 1. COM-B behaviour change model [(1)]

1) West, R., & Michie, S. (2020). A brief introduction to the COM-B Model of behaviour and the PRIME Theory of motivation [v1]. Qeios.5

How to use this workbook?

1. This workbook is a resource you can use to prepare yourself for eating in a social setting and to take with you when you go out.
2. You can use it to refresh your memory on eating in a public setting before you go out.
3. The activities in this workbook involve reflection and keeping a log of symptoms and emotions before, during and after eating in a social setting. You can come back to the workbook anytime you wish to note down the information
4. This workbook is designed to be personalised and adapted based on your personal experiences and preferences. Therefore, please feel free to add what works for you to make this a valuable resource for yourself.
5. The activities suggested in this workbook helped other people living with Achalasia, and this workbook was co-designed using their input.
6. This workbook can be used individually or in groups. If you wish to connect with others to use this workbook, we can link you up. (See Appendix A for more details)

Capability

In this workbook, we are concentrating on eating in a social setting. This component comprises the state of mind of the individual including perceptions, beliefs and emotions, knowledge and skills, and physical strength and ability.

The following **quotes** are the activities used by other people living with achalasia.

“I accept my condition and try to eat what I can eat confidently.”

“If I cannot finish my meal, I ask the restaurant to pack my meal and I take it home.”

“I ask for smaller portions and plenty of sauce when I go to eat out.”

“I warn my friends in advance, that sometimes I have to reject their food and it has nothing to do with their cooking and it is because of my condition.”

“I speak to the restaurant before I plan to eat out to make sure they have soft foods such as soup.”

Activity

It is useful to reflect when you eat in a social setting and note down your thoughts, emotions, and surroundings.

Event details:

Reflect on the last time you ate in a social setting.

- Where did you go out to eat? Please write the name of the place or describe the environment you were in.

  Name the venue: ……………………

  Was this venue,
  ☐ Somewhere new?
  ☐ A place which you always visit?

  How accommodating was the venue: (E.g., staff, menu, table location etc.)

- Who were you with?
  ☐ Friend
  ☐ Partner
  ☐ Family member

  Other people:
  ……………………
  ……………………

- When did you go out to eat? You can write the day, date or actual timing of your food. (Circle from the following or write down in the space provided)

  E.g. breakfast, brunch, lunch, dinner
  Others.................................... ....
  ....

- What did you eat? You can write the types of food you ate. (Circle from the following examples or write down in the space provided)

  E.g. soup, fizzy drink, food with lots of gravy

  Other foods: ....

  ....

Physical symptoms:

Did you experience any symptoms? You can write down any symptoms you experienced, such as pain, difficulty swallowing or anything else?
E.g. Pain other symptoms:..................
Regurgitation ....
Heartburn ....

What were the possible reasons?

....

....

Emotional symptoms:

How did you feel when you were out to eat? What emotions did you experience?

E.g., Nervous Excited Stressed

Happy Anxious Prepared

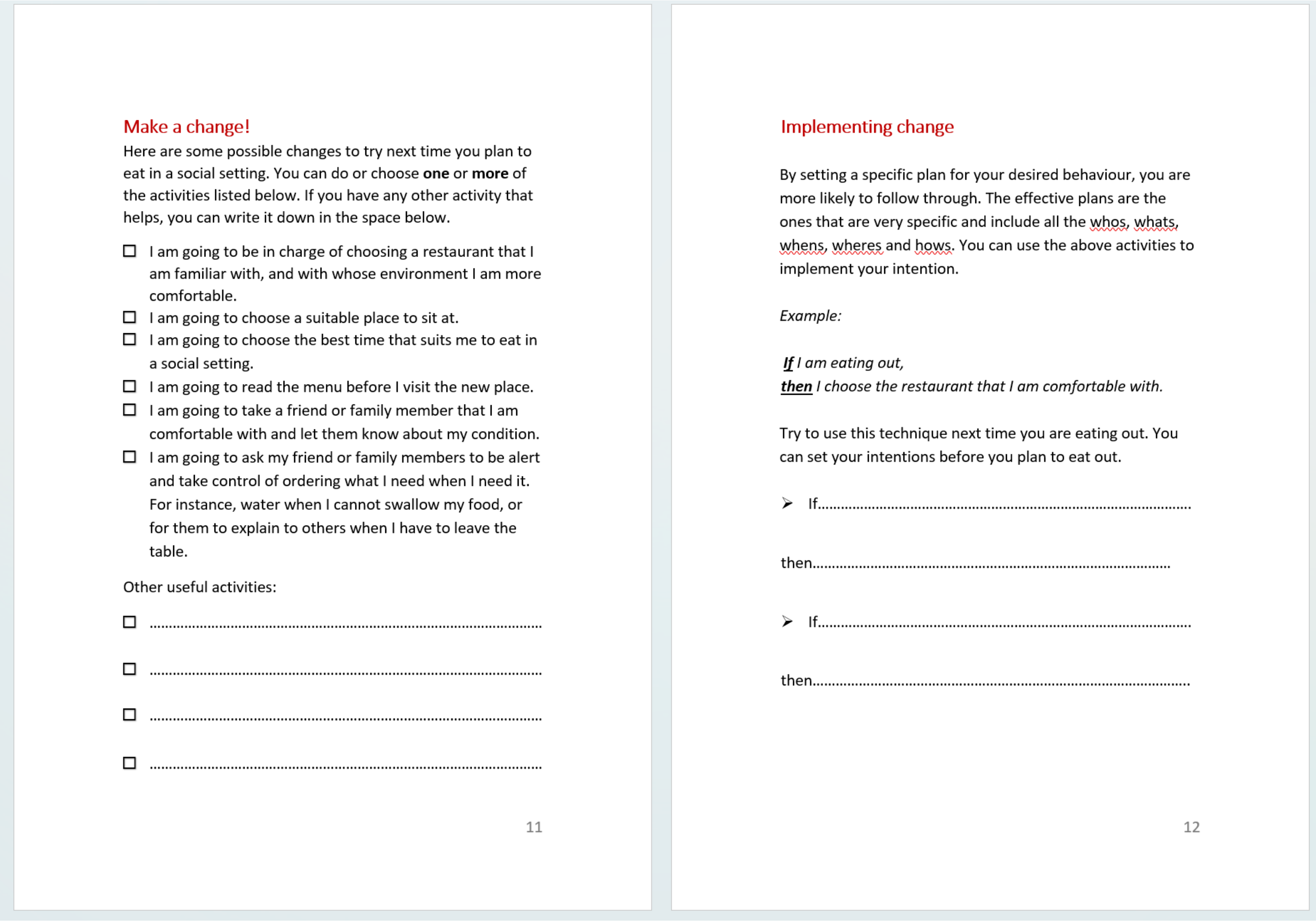
Relaxed

Other emotions: ....

What were the possible reasons?

....

....



Make a change!

Here are some possible changes to try next time you plan to eat in a social setting. You can do or choose **one** or **more** of the activities listed below. If you have any other activity that helps, you can write it down in the space below.

- ☐ I am going to be in charge of choosing a restaurant that I am familiar with, and with whose environment I am more comfortable.
- ☐ I am going to choose a suitable place to sit at.
- ☐ I am going to choose the best time that suits me to eat in a social setting.
- ☐ I am going to read the menu before I visit the new place.
- ☐ I am going to take a friend or family member that I am comfortable with and let them know about my condition.
- ☐ I am going to ask my friend or family members to be alert and take control of ordering what I need when I need it. For instance, water when I cannot swallow my food, or for them to explain to others when I have to leave the table.

Other useful activities:

- ☐ ....
- ☐ ....
- ☐ ....
- ☐ ....

Implementing change

By setting a specific plan for your desired behaviour, you are more likely to follow through. The effective plans are the ones that are very specific and include all the whos, whats, whens, wheres and hows. You can use the above activities to implement your intention.

Example:

If *I am eating out,*
then *I choose the restaurant that I am comfortable with.*

Try to use this technique next time you are eating out. You can set your intentions before you plan to eat out.

- If..

then..

- If..

then..

If you need to add any extra information you can use the space below to note down your thoughts, emotions and possible changes.

Opportunity

This section refers to external factors that make a behaviour possible and can include physical and social opportunities. You can also use the Attention card produced by Achalasia Action (ACAC) to help inform your waiter/chef of your needs. (See Appendix B)

The following **quotes** are the activities used by other people living with achalasia.

“I think it is the people around you knowing what’s wrong with you that does help you relax at mealtimes.”

“I try not to hide my condition, as that makes me stress less about it.”

“When I cannot eat, I stop eating and I just walk around or walk to the toilet.”

“I’d ask for a child’s portion and extra plate and I start moving food and sharing with the table.”

“Never eat when you are stressed or if you’ve had a major disagreement with someone.”

“I can’t eat too late at night, and it tends to be at lunchtime or like a 5:00 pm type meal.”

Activity

Reducing negative emotions

The following prompts helped others to eat in a social setting more comfortably. Next time you are eating in a social setting, you can use them.

You can also refer to **Appendix C,** cut out the desired prompts or take a photo and take them with you when eating in a social setting.

Prompts

- I can take someone with me to help with explaining my condition and to ask for water when I need it.
- I do not have to order a starter, a main course, and a dessert.
- I am here to socialise with people I do not necessarily have to finish my meal.
- I can take my time to finish my meal.
- I am here to enjoy the company.
- I do not have to finish my food.
- I will eat what I can.
- [Please add if necessary]……………………………………………
- ……………………………………………………………………………
- ……………………………………………………………………………

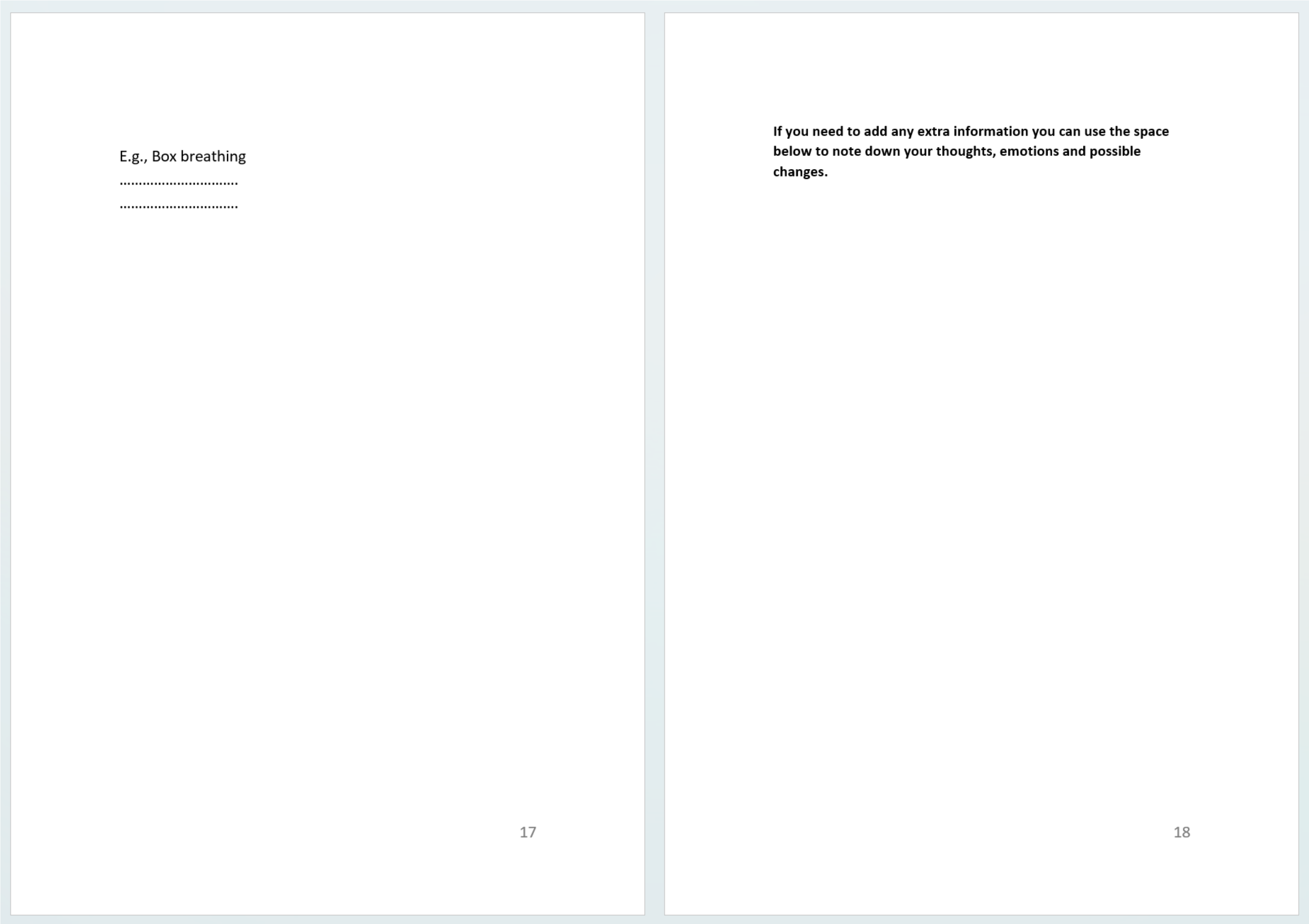
Activity

Simple Breathing Exercise

Inhale slowly and deeply through your nose. Keep your shoulders relaxed and sit in an upright position.
Exhale slowly through your mouth. As you blow air out, purse your lips slightly, but keep your jaw relaxed.
Repeat this breathing exercise. Do it for several minutes until you start to feel better.

Reddy, S. (2021, January 29). Breathing Techniques for Stress and Anxiety. Https:/Swaafrica.Org/Breathing-Techniques-for-Stress-and-Anxiety/. Retrieved June 6, 2022, from https://swaafrica.org/breathing-techniques-for-stress-and-anxiety/

This is just one example of many breathing exercises. You can use any that you have used in the past and suits you best.
You can record the name of the exercise below:



E.g., Box breathing
……………………………
……………………………

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If you need to add any extra information you can use the space below to note down your thoughts, emotions and possible changes.

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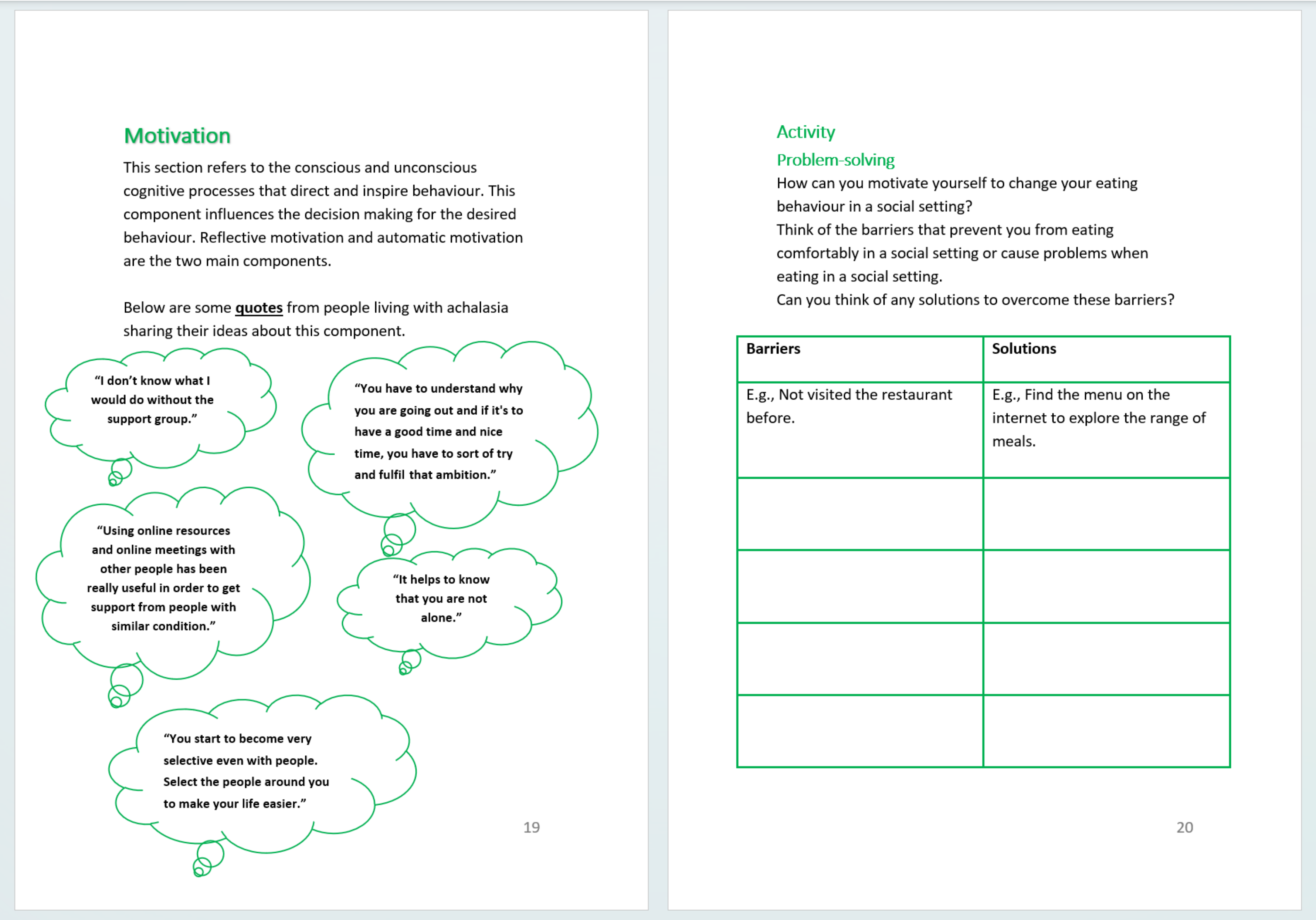


Motivation

This section refers to the conscious and unconscious cognitive processes that direct and inspire behaviour. This component influences the decision making for the desired behaviour. Reflective motivation and automatic motivation are the two main components.

Below are some **quotes** from people living with achalasia sharing their ideas about this component.

"I don't know what I would do without the support group."

"You have to understand why you are going out and if it's to have a good time and nice time, you have to sort of try and fulfil that ambition."

"Using online resources and online meetings with other people has been really useful in order to get support from people with similar condition."

"It helps to know that you are not alone."

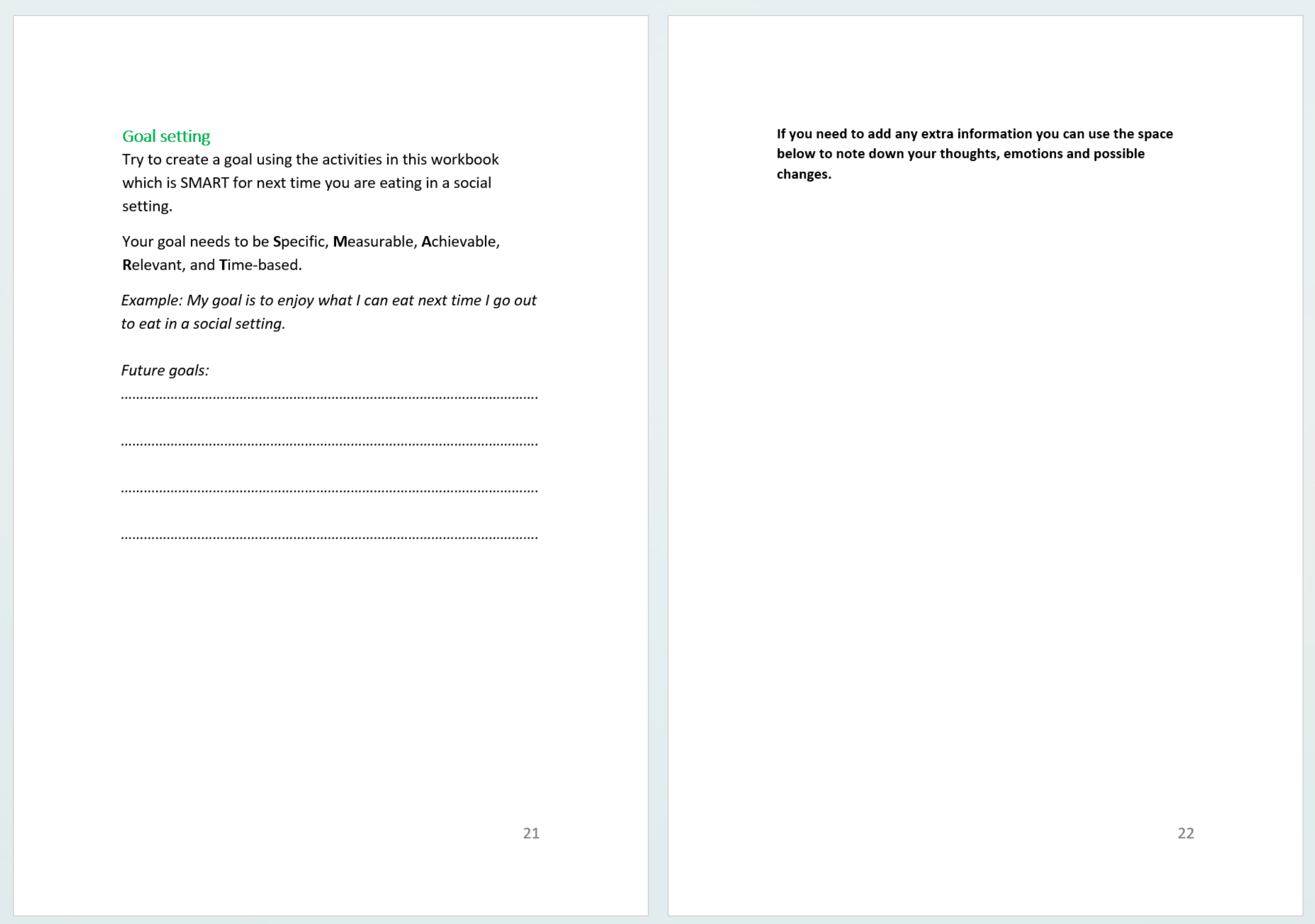
"You start to become very selective even with people. Select the people around you to make your life easier."

Activity

Problem-solving

How can you motivate yourself to change your eating behaviour in a social setting?
Think of the barriers that prevent you from eating comfortably in a social setting or cause problems when eating in a social setting.
Can you think of any solutions to overcome these barriers?

Barriers	**Solutions**
E.g., Not visited the restaurant before.	E.g., Find the menu on the internet to explore the range of meals.



Goal setting

Try to create a goal using the activities in this workbook which is SMART for next time you are eating in a social setting.

Your goal needs to be **S**pecific, **M**easurable, **A**chievable, **R**elevant, and **T**ime-based.

Example: My goal is to enjoy what I can eat next time I go out to eat in a social setting.

Future goals:

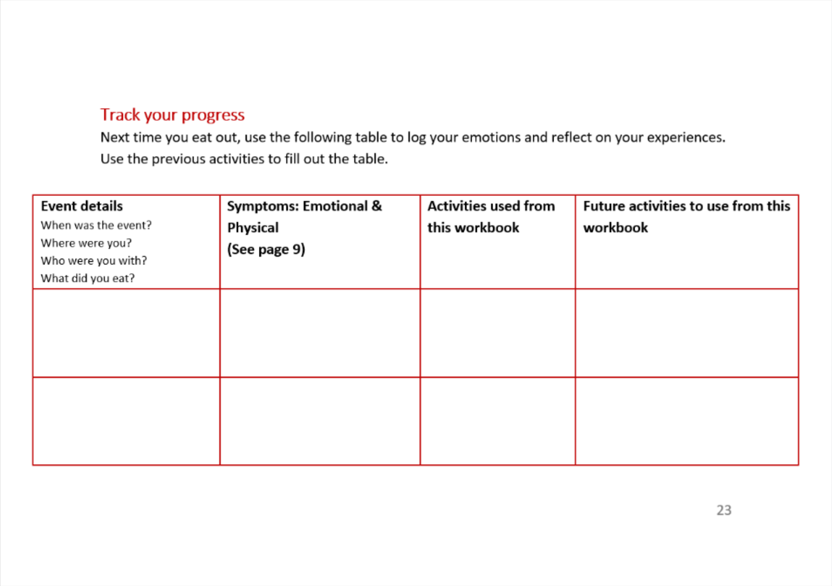
……………………………………………………………………………………………

……………………………………………………………………………………………

……………………………………………………………………………………………

……………………………………………………………………………………………

If you need to add any extra information you can use the space below to note down your thoughts, emotions and possible changes.



Track your progress

Next time you eat out, use the following table to log your emotions and reflect on your experiences.
Use the previous activities to fill out the table.

Event details When was the event? Where were you? Who were you with? What did you eat?	**Symptoms: Emotional & Physical** **(See page 9)**	**Activities used from this workbook**	**Future activities to use from this workbook**

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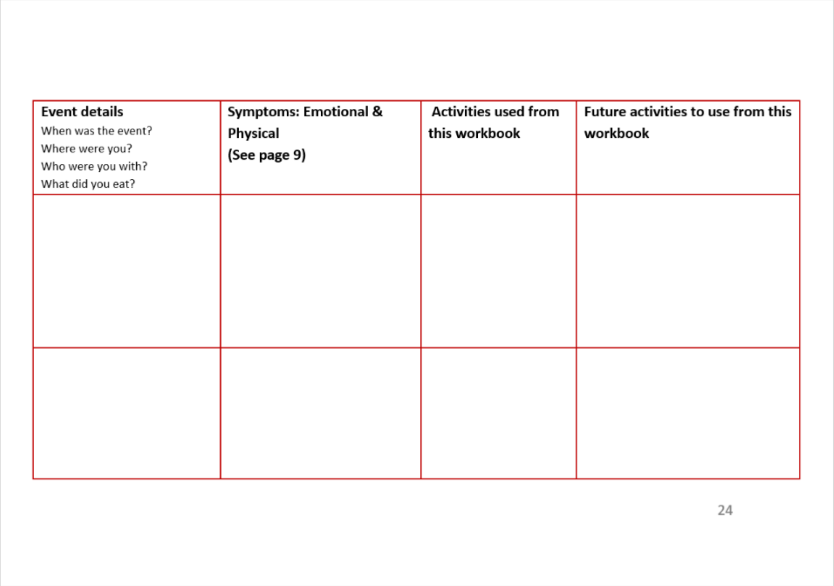
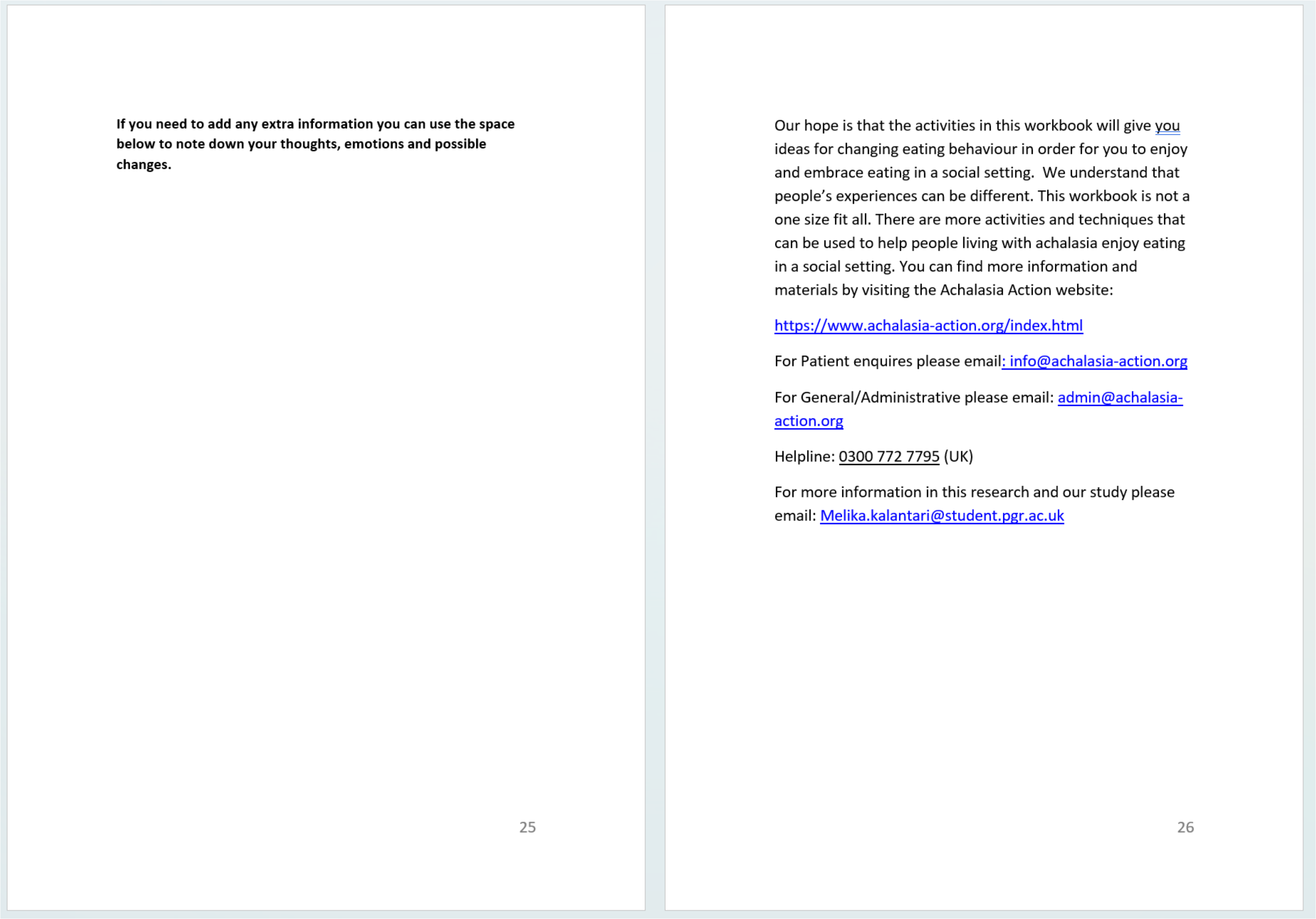


Event details When was the event? Where were you? Who were you with? What did you eat?	**Symptoms: Emotional & Physical** **(See page 9)**	**Activities used from this workbook**	**Future activities to use from this workbook**

24



If you need to add any extra information you can use the space below to note down your thoughts, emotions and possible changes.

25

Our hope is that the activities in this workbook will give you ideas for changing eating behaviour in order for you to enjoy and embrace eating in a social setting. We understand that people's experiences can be different. This workbook is not a one size fit all. There are more activities and techniques that can be used to help people living with achalasia enjoy eating in a social setting. You can find more information and materials by visiting the Achalasia Action website:

https://www.achalasia-action.org/index.html

For Patient enquires please email: info@achalasia-action.org

For General/Administrative please email: admin@achalasia-action.org

Helpline: 0300 772 7795 (UK)

For more information in this research and our study please email: Melika.kalantari@student.pgr.ac.uk

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Appendix A

- If you would like us to link you up with others for additional support, please let us know.
- You can do this by emailing the research team at Melika.kalantari@student.pgr.ac.uk.
- We will then put you in contact with others who are also using this workbook and interested in linking up for support.
- By doing this you can share tips, activities, and experiences.
- By joining this group, you are consenting to share your personal details with others.
- If those you are linked with are not communicating you can change your group by contacting the research team.
- After you are linked with others you can talk and share your experiences with others.
- You can also decide how often you can speak to others.
- Please bear in mind that everyone's experiences are unique and there are no right or wrong tips, activities, or interventions.

Appendix B

The Attention card produced by ACAC to help inform your waiter/chef of your needs. You can access these card on the official website of Achalasia Action.

https://www.achalasia-action.org/index.html

Restaurant Attention Card

Thank you for agreeing to cook for me. I suffer from a swallowing condition called Achalasia. This makes certain foods difficult for me to swallow. To make swallowing easier and to enjoy my experience with you, I have a special need for:

- Smaller portions than usual
- lots of gravy or sauce
- Vegetables to be mashed or well cooked

I would be very grateful if you could accommodate my needs, and keep any attention to a minimum.

ACHALASIA ACTION

www.achalasia-action.org

Uniting for a Rare Swallowing Condition

ACHALASIA ACTION

Special Dietary requirements:

Because of a medical condition, please provide me with a small portion

Thank you for your help and understanding

Achalasia Action (reg charity no 1187367 in England & Wales)

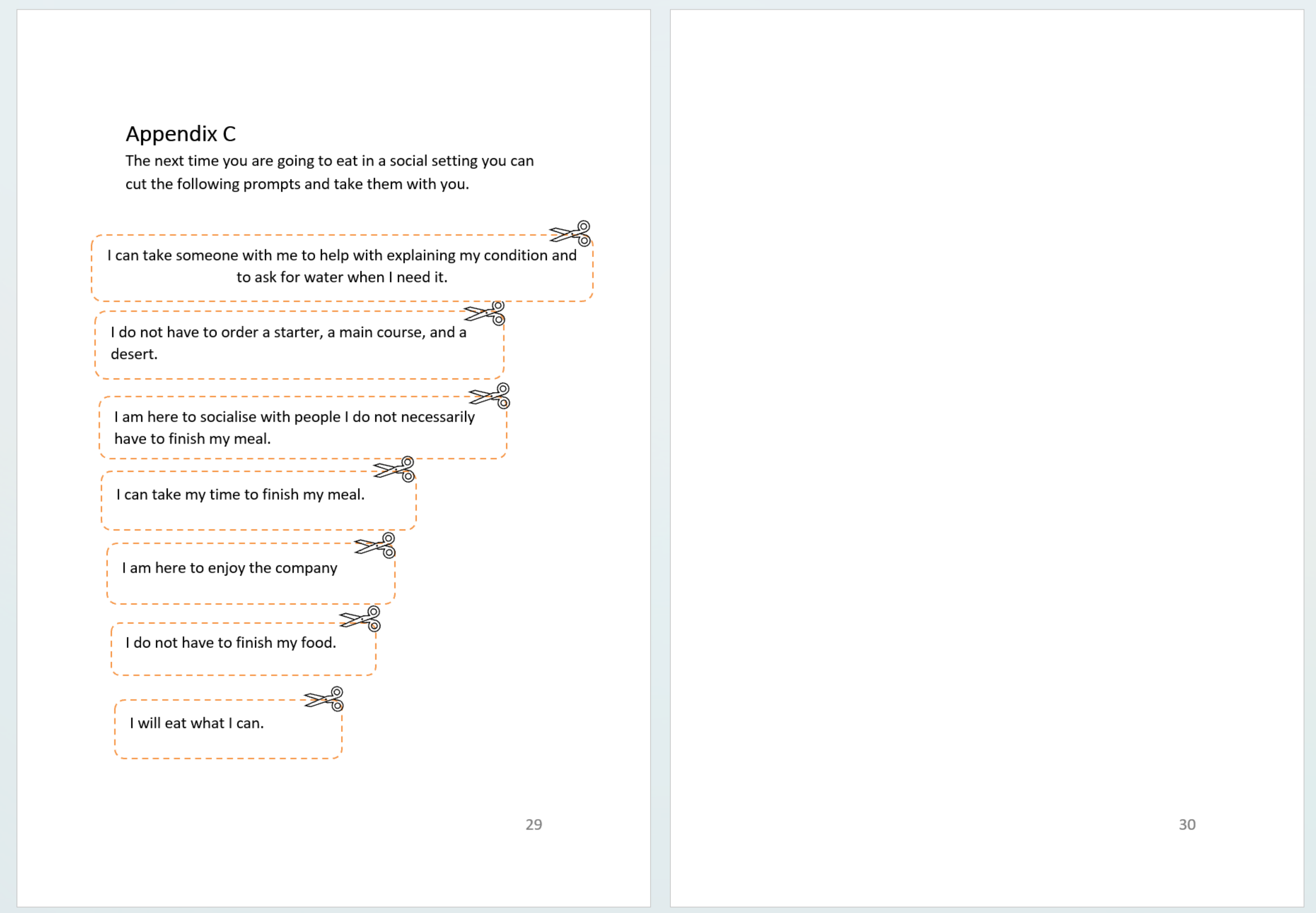
ACHALASIA ACTION

Achalasia is a rare medical condition experienced by around 6,000 people in UK that affects swallowing and the ability of food to pass through the oesophagus and into the stomach.

Achalasia Action is a charity that welcomes support to promote awareness, education and research about this disease.

Website: www.achalasia-action.org
Email: info@achalasia-action.org
Twitter: @AchalasiaAction
Facebook: www.facebook.com/achalasiaaction
Donate: www.achalasia-action.org/donate-to-achalasia-action.html

Achalasia Action (reg charity no 1187367 in England & Wales)



Appendix C

The next time you are going to eat in a social setting you can cut the following prompts and take them with you.

I can take someone with me to help with explaining my condition and to ask for water when I need it.

I do not have to order a starter, a main course, and a desert.

I am here to socialise with people I do not necessarily have to finish my meal.

I can take my time to finish my meal.

I am here to enjoy the company

I do not have to finish my food.

I will eat what I can.