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Protocol for a feasibility and acceptability study using a brief ACT-based intervention for people from Southwest Wales who live with persistent pain

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ABSTRACT

Introduction Persistent pain affects a large percentage of the UK population and its burden has wide ramifications that affect physical, psychological, socioeconomic and occupational status. Pain has a significant impact on people's well-being and quality of life. Some of the most common comorbidities found in this population are depression and anxiety and also maladaptive behaviours such as fear avoidance and catastrophising.

Methods and analysis This is a protocol for a study assessing the feasibility and acceptability of a novel Acceptance and Commitment Therapy (ACT)-based intervention for people from Southwest Wales who live with persistent pain. A group of 12 participants will be recruited through the Health and Wellbeing Academy (Swansea University). After being referred by an Osteopath, and attending a brief meeting with the researcher, the participants will take part in six sessions over six consecutive weeks. 'A Mindful Act' is an ACT-based group programme aiming to teach people how to develop more acceptance and self-compassion, be more mindful and clarify personal values in order to live a more rich and meaningful life. The main outcomes will include the feasibility of the recruitment process and the measurement tools, the acceptability of the intervention for both the participants and the Osteopaths and the adherence to the programme. In order to measure acceptability of the intervention, qualitative interviews will be conducted to provide an insight into peoples' experiences of taking part. Data will be analysed using Thematic Analysis, with the use of NVIVO 10. In addition, quantitative data will be collected at baseline, on completion of the programme and at 1 month and 3 months follow-up to reveal any differences in psychological flexibility, depression, anxiety, fear avoidance and general health status. The findings will help enhance the intervention by making appropriate modifications to the processes and procedures involved, following the recommendations made by the Medical Research Council framework. A larger scale study is envisaged to follow, in order to investigate the full effectiveness and cost-effectiveness of 'A Mindful Act'.

Ethics and dissemination This study was approved by the College of Human and Health Sciences Research Ethics Committee at Swansea University in December 2017. The findings will be disseminated through various means including: the first author's PhD thesis, peer-reviewed journals as well as well as national and international conferences and public events.

Strengths and limitations of this study

- This intervention is fostering an interdisciplinary collaboration between Psychology and Osteopathy.
- The data collection will be done via multiple methods.
- Due to the nature of this acceptability and feasibility study, it will not possible to randomise participants.
- The conclusions of this study will be limited due to the small number of participants and the lack of control group.
- Running more than one group would have been a better test of feasibility; however, it was not possible due to time and resource requirements.

INTRODUCTION

While most people live relatively pain-free lives, with occasional acute pain in the event of an injury, there are a large percentage of people who experience persistent pain. Recent prevalence data suggest that between one-third and one-half of the UK population of (approx. 28 million adults) are affected by this condition.[1] Pain is essentially an alarm system, warning us of a potential danger of injury; however, for people with long- term pain, this is a weekly or daily occurrence that has a significant impact on their psychological well-being and quality of life. The burden of pain also has wide ramifications that affect physical, psychological, socioeconomic and occupational status.[2 3]

Persistent pain is often accompanied by distress. There is a large percentage of people living with pain (4.7%–22% in population-based studies and from 5.9% to 46% in

primary care studies) experience depression.[4 5] There is also increasing evidence to support the co-occurrence of persistent pain and anxiety disorders such as generalised anxiety disorder, panic attacks, social anxiety or post-traumatic stress disorder.[6–8] Persistent pain affects people's quality of life significantly, making everyday activities (such as doing household chores) difficult. People living with pain are also less able or unable to sleep and report that pain has a significant effect on their social relationships.[9] Another significant issue that affects this population is pain-related fear of movement (kinesiophobia), which then leads to hypervigilance and avoidance behaviours. Similarly, people with persistent pain often catastrophise. This is seen as exaggerated negative thoughts and feelings in response to actual or anticipated pain.[10]

Although traditional Cognitive behavioural Therapy (CBT) has been a successful treatment for long- term pain, demonstrating reductions in pain and improvements in functioning, new methods like Acceptance and Commitment Therapy (ACT) can offer an important avenue for many patients living with pain.[11] Although ACT and traditional CBT share many features, the distinction between these two approaches consists in the emphasis of ACT on acceptance and engaging in behaviour in line with one's values over cognitive restructuring and symptom reduction.[12] The ultimate goal of ACT is to improve functioning by increasing psychological flexibility and the ability to act according to personal values, even in the presence of negative experiences. ACT helps people clarify what is truly important, then use that knowledge to guide, inspire and motivate change in order for the individual to live a more full and meaningful life.

Using the ACT model for persistent pain is supported by empirical research.[13] A recent meta-analytic review of 25 RCTs (1285 patients with chronic pain) comparing acceptance and mindfulness-based interventions to the waitlist, treatment-as-usual and education or support control groups concluded that patients responded well to ACT and mindfulness interventions and that the benefits persisted after the treatment.[14] The effect sizes reported post-treatment ranged from small (on all outcome measures except anxiety and pain interference) to moderate (on anxiety and pain interference) and from small (on pain intensity and disability) to large (on pain interference) at follow-up. The authors suggested that although acceptance and mindfulness interventions are not superior to traditional CBT treatments, they are considered good alternatives. A similar review found ACT effective particularly in decreasing stress and enhancing general functioning compared with inactive treatments.[15] Furthermore, a more recent review suggested that ACT was more effective than treatment as usual on a number of outcomes such as functioning, anxiety and depression.[16] There were significant medium to large effect sizes for pain acceptance and psychological flexibility. Furthermore, participation in ACT-based programmes is known to reduce medication use and healthcare utilisation and help people return to work after long periods of absence.[17]While there is support for the use of ACT with persistent pain populations, more methodologically robust trials are needed to compare the effectiveness of ACT with other psychologically based approaches.[18]

The last decade has witnessed an increasing emphasis on self-management, which has been defined as being able to manage the symptoms; the treatment, the consequences and the life style change necessary when living with a long-term condition.[19] People who experience persistent pain are known to encounter barriers such as: fatigue, low levels of energy, low mobility and sometimes inability to travel.[20] All of these barriers hinder individuals from accessing support resources and committing to therapies delivered over a longer period of time. Brief interventions can be advantageous for people living with persistent pain, as they are short, likely to be more acceptable and they simultaneously promote self-management skills. Additionally, from a cost-effectiveness point of view, brief interventions are less expensive, time limited, structured and goal-directed. Results from a brief (four session) group- based ACT intervention carried out in Southwest England with persistent pain patients revealed that the use of ACT is feasible in general practice and considered acceptable by patients.[21] One of the advantages of this model consists in its transdiagnostic[i] nature and the fact that it can be adapted or integrated into different contexts and settings.

Pain may become an area easy to ignore in the current political climate, as it may be seen by some as a non-threatening condition whose consequences are not immediately visible. It is essential, therefore, to highlight the importance of pain management in reducing some of the suffering and the personal and societal costs associated with this condition. Setting realistic evidence-based standards that will guide the delivery of pain services across the UK is equally important. According to the Core standards for pain management services in the UK (published in 2015), NHS England adopted a 'House of Care' model in managing patients with persistent pain.[22] This model takes into account the resources and expertise of people living with long-term conditions and provides a holistic approach to support them in achieving the best outcomes possible (NHS England). In Wales, the NHS is embracing the prudent healthcare principles.[23] Informed by the work of the Bevan commission, these principles emphasise the establishment of an early biopsychosocial assessment within the community and making sure that self-management is available early to the patients with long-term pain conditions. The guidance also recommends fully exploiting the resources that are already available as well as identifying interventions and initiatives that are cost-effective and promoting healthcare that fits the needs of the

[i]Transdiagnostic—designed to alleviate a range of psychological conditions.

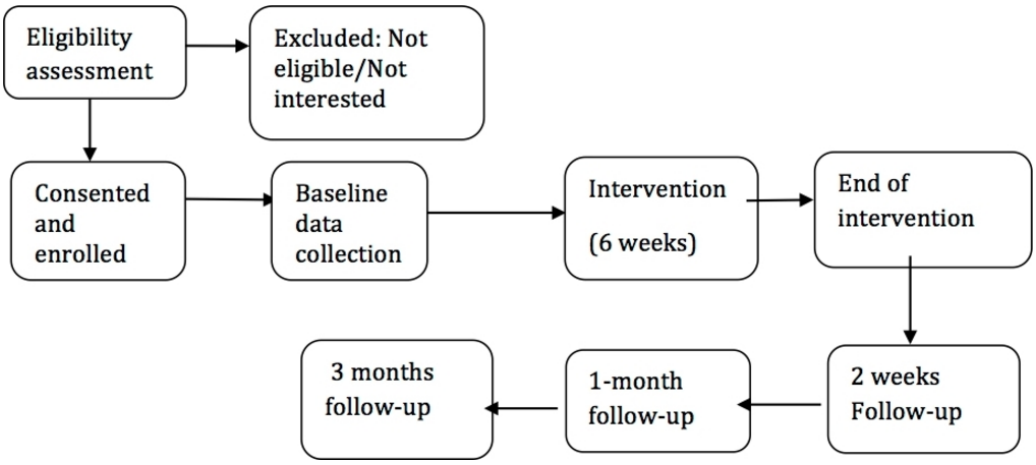

Figure 1 Flow diagram of the study designed to assess the feasibility and acceptability of a novel psychosocial intervention ('A Mindful ACT').

patients. In recent years, chronic pain services in Wales have shown improvement; however, there is still some variation in provision and delays in accessing appropriate treatment.[24] Further work is necessary to improve access to pain management programmes and specialised interventions.

Following a preliminary qualitative study to understand more about the experiences and needs of people with persistent pain, we designed a brief psychosocial intervention based on ACT principles for people from Southwest Wales who live with persistent pain who also present psychological comorbidities (such as depression and anxiety) and maladaptive coping strategies (catastrophising and/or fear avoidance). The results obtained from the focus groups and qualitative interviews have informed the development of the intervention.

'A Mindful Act' is a brief ACT-based programme designed for people living with persistent pain. This intervention aims to teach people how to develop more acceptance and self-compassion, be more mindful and clarify their personal values in order to live a more rich and meaningful life. The development of this intervention has followed the recommendations of the updated Medical Research Council (MRC) guidance for developing complex interventions.[25] The second stage (feasibility/piloting) of the development and evaluation process includes testing procedures, estimating recruitment/retention and determining sample size. The guidance emphasises the importance of assessing feasibility and acceptability. An early evaluation of the acceptability of a complex intervention can highlight aspects of the interventions that can be modified before a definitive trial.[21 26] According to the MRC guidance, this stage is very useful in providing insights regarding the appropriateness of the procedures, the recruitment process, participant retention and how acceptable the participants find the programme. The MRC guidance also suggests using a mixture of quantitative and qualitative methods to better understand barriers to participation and estimate response rates.

Objectives

This study aims to investigate the feasibility and acceptability of a novel, ACT-based psychosocial programme (as described by the MRC framework) for people from Southwest Wales who live with persistent pain.

METHODS AND ANALYSIS

Study design

This is a mixed-method study focusing on determining the feasibility and acceptability of a novel ACT-based intervention. The main outcomes will include the feasibility of the recruitment process and the measurement tools, the acceptability of the intervention for both the participants and the Osteopaths and adherence to the programme. Qualitative interviews will be conducted to provide an insight into peoples' experiences of taking part. Data will be analysed using Thematic Analysis, with the use of NVIVO 10. Two researchers will be validating the results. Quantitative data will be collected at baseline, on completion of the programme and at 1 month and 3 months follow-up and will include the following outcomes: psychological flexibility, depression, anxiety, fear avoidance and general health status (see figure 1).

Participants

Participants will be recruited through the Health and Wellbeing Academy (HWBA; within Swansea University). There will be a group of 12 participants taking part in 'A Mindful Act'. This group size was considered ideal due to the nature of this intervention, in order to allow group work but at the same time provide the necessary therapeutic space for each of the participants. Eligibility criteria are as following: being over 18 years of age, living with persistent pain,[ii] experiencing one or more of the following: depression, anxiety, fear avoidance, catastrophising (according to their medical record); able to read,

[ii]Persistent pain is defined as pain that lasts or recurs for more than 3–6 months (Merskey and Bogduk, 1994).

Table 1 Recruitment stages

Recruitment stages	
First stage	**Second stage**
Osteopaths will identify adult patients with persistent non-malignant pain as well as one or more of the following: depression, anxiety, fear avoidance and/or catastrophising (based on medical history/self-declared). Osteopaths will apply the inclusion criteria: patients who are able to read, write, speak and comprehend English; patients able and willing to commit to six consecutive weekly sessions, to be interviewed about taking part and to fill in questionnaires at four time points. Osteopaths will also apply the exclusion criteria: patients with malignant pain (medical history); patients who experience severe mental health issues or addiction problems (medical history/self-declared); patients who are currently undergoing psychological treatment (self-declared/medical history).	The main investigator will ask patients some questions about their current state of health (in order to find out more about potential physical limitations that might interfere with participation. The main investigator will reiterate the nature of the intervention (there will a total of six sessions delivered in a group, complemented by homework and a one to one interview approximately 2 weeks after the last session). The patients will be able to ask whatever questions they might have regarding the intervention.

write and speak English and also able to commit to six consecutive weekly sessions. Potential participants will be excluded if they: experience severe mental health issues, addictions or are currently undergoing psychological treatment.

Recruitment

The recruitment will be carried out in partnership with the Osteopaths within the Osteopathy Clinic at Swansea University[iii] and will be performed in two stages (see table 1).

The Main Investigator will brief the Osteopaths in regards to 'A Mindful Act' and provide an information package with all the relevant information about the intervention. The Osteopaths will identify patients who are eligible (by applying inclusion and exclusion criteria). Following that, the MI will meet the patients in person in order to find out more about their general health and also to reiterate the nature of the intervention and answer questions.

The patients considered eligible will be handed an information sheet and a consent form. They will be given 2 weeks to return the signed consent form (if they decide to participate). The CI will send an email to remind the participants to bring along the consent form to the introductory session.

Intervention setting

'A Mindful ACT' will be delivered within the Health and Wellbeing Academy at Swansea University (Singleton Campus), a setting already familiar to the patients. A multipurpose room with plenty of space to move around, natural light, comfortable chairs within a modern, state of the art building was chosen to host the six sessions. Participants will be encouraged to bring yoga mats or cushions for the Body Scan exercise. Reminders will be sent via email 1 day before each session. More information about the different elements of the intervention can be found in online supplementary appendix 1.

Outcome measures

Primary and secondary outcomes

The primary outcomes include the acceptability of the proposed intervention, the feasibility of recruitment and measurement and the adherence to the intervention.

Feasibility

Recruitment process

- Number of people referred from Osteopaths and eligible for screening.
- Number of people attending interview with researcher.

Feasibility of measurement tools

- Time taken to fill in questionnaires.
- Missing data from questionnaires.
- Follow-up response rates (1 month and 3 months follow-ups).

Acceptability

Prospective acceptability

- Barriers (screening interview).
- Burden (reasons for not taking part/discontinuation or dropping out).

Intervention coherence and adherence

- Number of sessions attended.
- Homework completion (workbook entries, Mindfulness diary).
- Time dedicated to homework practice.
- ACT basic definitions quiz (six questions regarding ACT principles).

Experience (satisfaction, perceptions)

Qualitative interview (end of programme).

Acceptability of the programme to Osteopaths

Focus Group.

Secondary outcomes

The secondary outcomes (measured at baseline, on completing of the programme, at 1 month and 3 months

[iii] Permission was obtained from the Director of Academic and Clinical Operations at Health and Wellbeing Academy, to recruit through the Osteopathy clinic. The Osteopaths will be M.Ost students practicing in the clinic.

follow-up) are only meant to provide some preliminary data on outcomes such as depression and anxiety, acceptance of pain, mindfulness, fear avoidance and quality of life.

Hospital Anxiety and Depression Scale (HADS)

The HADS is a self-assessment scale designed to detect states of depression, anxiety and emotional distress.[27] Patients are asked to reflect on how they have been feeling during the past week and respond to 14 items (seven for anxiety and seven for depression). HADS is advantageous as it is brief and simple to use (it takes on average 2–5 min to complete). Also, it demonstrated good factor structure, intercorrelation, homogeneity and internal consistency.[28] This scale has been routinely used in research involving patients with persistent pain.[29]

Mindfulness Attention and Awareness Scale (MAAS)

MAAS is one of the most commonly used measures of mindfulness in research.[30] The 15-item scale assesses awareness of the present moment. The 15 statements refer to everyday experiences and are rated on a scale from 1 to 6 according to their frequency (1—almost always, 6—almost never). MAAS has good psychometric properties: internal consistency (α=0.82), test-retest reliability (α=0.82) and convergent validity with related measures.[31] Increases in the practice of mindfulness have been related to positive outcomes such as: a better ability to handle long-term pain, fibromyalgia and physical stress.[32 33]

Chronic Pain Acceptance Questionnaire (CPAQ-R)

The CPAQ-revised scale has been designed to measure acceptance of pain. Developing more acceptance is related to fewer attempts to avoid or control pain and also with more engagement in valued activities. The items on the CPAQ are rated from 0 to 6 (0—never true and 6—always true). Higher scores indicate a higher level of acceptance. CPAQ has two factors: activity engagement and pain willingness. They significantly predict pain-related disability and distress. The CPAQ demonstrates excellent internal consistency (0.78–0.82) and validity and shows moderate to high correlations with measures of avoidance, distress and daily functioning.[34]

Fear-Avoidance Beliefs Questionnaire (FABQ)

FABQ is based on the fear avoidance model, which explains why some patients with acute pain recover while others develop chronic pain.[35] This questionnaire measures patients' fear of pain and avoidance of physical activity. FABQ has two subscales (Work and Physical activity) helping identify beliefs about how work and physical activity affect their pain. There is a strong relationship between elevated fear avoidance beliefs and chronic disability. Avoidance may lead to an increase in disability, reduced activity levels and adverse physical and psychological effects.[36] FABQ shows good reliability (0.97) and validity. FABQ is correlated with Roland and Morris Disability Questionnaire (r=0.455, =0.000) and with Tampa Scale of Kinesiophobia, another measure of fear avoidance (0.53 for FABQ work subscale and 0.76 for the physical activity subscale).[37]

EQ-5D-5L[iv]

This measure was introduced by the EuroQol Group in 2009 to improve the instrument's sensitivity and to reduce ceiling effects. EQ-5D comprises five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. The patient is asked to indicate his health state by ticking the box corresponding to the most appropriate statement in each of the dimensions. The resulting digits can be combined into a five-digit number describing the patient's health status. The Visual Analogue Scale records the patient's self-rated health on a vertical scale, where the end points are 'the best health you can imagine' and 'the worst health you can imagine'. EQ-5D is easy to complete and to score. In addition, the results can be used in health economic evaluations by performing QALY[v] calculations (converting the five digit combinations into numbers that reflect overall quality of life).

Intervention

'A Mindful Act 'is a brief programme composed of six two-hour sessions, taking place over six consecutive weeks (see table 2). Based on ACT principles, this intervention will focus on increasing psychological flexibility. The intervention will concentrate on: basic ACT tenets, mindfulness practice, holding self-stories lightly, practicing self-compassion and self-care, acceptance and values identification and committed action towards a meaningful life. 'A Mindful Act' is largely built up of freely accessible material from Russ Harris and Kelly Wilson. The sessions will consist of: group activities, mindfulness exercises, reflections on the homework practice and movement breaks (see table 2). All the participants will receive a workbook containing homework exercises based on each week's topic. They will be able to retain the workbook after the completion of the programme. The main investigator will encourage the homework exercises; however, it is up to each participant how much they want to engage with it.

Facilitators

All six sessions will be delivered by the main researcher with the help of an assistant, who will provide support with group activities and help with data collection. The main investigator has a background in health psychology and is also trained in delivering ACT based interventions. The programme assistant is a qualified osteopath with experience of supporting people with persistent.

[iv]The results will be used in an ulterior health economic analysis, to assess the cost-effectiveness and cost-utility of the intervention.

[v]QALY means quality-adjusted life year and is a summary measure of health outcome used in economic evaluations; One QALY is equal to 1 year in perfect health.

Table 2 Overview of the intervention

Sessions	Content
Week 1—Introduction	► Welcoming the participants and introducing the team ► A brief overview of the purpose of the programme and the content of each session ► Explaining basic ACT tenets ► The nature of persistent pain and getting caught up in the struggle ► Homework- Attempted solutions and their long-term effects exercise (Russ Harriss)
Week 2—Learning to be mindful	► Reflections on the homework, opportunity for questions ► What is Mindfulness and how is it useful? ► Embedding Mindfulness into daily activities (eating, walking, communication, acts of kindness) ► Group body scan exercise (20 min) ► Homework: Daily Mindfulness practice sheet
Week 3—Defusion	► Reflecting on Mindfulness practice ► What is defusion and how to hold self-stories lightly ► Brief Observer self exercise ► 'Passengers on the bus' metaphor and group discussion ► Homework based on 'Passengers on the bus'
Week 4—Self-compassion and self-care	► Reflection on homework and Mindfulness practice ► Self-compassion explained ► Self-care activities ► Eight practices for recovery and a life well-lived (Kelly G. Wilson) ► Homework: Growing circle of self-care (Kelly G. Wilson)
Week 5—Acceptance and values	► Reflecting on self-care and self-compassion ► Acceptance as opposed to avoidance ► Acceptance physical exercise ► What are values and why are they important? ► Matrix interview exercise (Kelly G. Wilson) ► Homework: Values clarification exercise
Week 6—Committed action—a way forward	► Brief reflection on values ► Committed actions towards a rich, meaningful life ► The willingness and Action Plan exercise (Russ Harriss) ► How will you take this forward? ► Final conclusions and reminder about follow-up

ACT, Acceptance and Commitment Therapy.

Patient involvement statement

A preliminary qualitative study has been conducted to enhance our understanding of people's experiences of living with persistent pain and to inform the development of this intervention. Patients' perspectives of managing pain and the way they reconcile acceptance of pain with moving forward were explored through a focus group. Acceptability and willingness to engage with the intervention were also considered. An additional focus group was conducted with osteopaths to achieve a better understanding of their experiences supporting this population.

The patients' reported needs, barriers and preferences have influenced the structure, content and the mode of delivery of the intervention. The majority of the participants expressed curiosity and interest in trying something novel. Some barriers identified were: the amount of time necessary to take part, travel time, side effects of medication, not being able to sit for long periods of time and being in pain, short attention span and not feeling well enough to participate. They have expressed a preference for group activities, the use of real life examples, videos and hands-on activities.

Planned data analysis

As this is primarily an acceptability and feasibility study, the analysis will focus on the key parameters necessary for conducting a future trial. Most of the analysis will be descriptive in nature.

Feasibility[vi] will be determined by assessing the recruitment process (number of participants referred, number of people attending an interview with the researcher) and also the measurement tools (by recording the time for filling in the questionnaires, number of items missing and the follow-up rates).

[vi] 'The feasibility and piloting stage includes testing procedures for their acceptability, estimating the likely rates of recruitment and retention of subjects and the calculation of appropriate sample size.' (Developing and evaluating complex interventions: the new Medical Research Council guidance).

Table 3 Qualitative interview

Acceptability and feasibility	How would you describe your experience of taking part in 'A Mindful Act' programme?
Process of change	What did you learn from this programme?
Acceptability	What was the aspect of the programme that you liked the most? What was your favourite activity (or session)?
Suggestions for further improvement	What did you least like about the programme? What do you think could be improved about 'A Mindful Act'?
Barriers	Were there any difficulties to taking part?
Process of change	Are there any changes in your perspective of living with pain? If the answer is 'Yes', what are they?
Implementing change	Do you practice Mindfulness? How often?
Process of change	Have you noticed any differences in your life as a result of taking part in 'A Mindful Act'? If 'yes', what are these differences?
Acceptability	Would you recommend this intervention to someone you care about?

Acceptability[vii] will be divided into three categories: prospective acceptability (how an individual feels about the intervention prior to participating), intervention coherence and adherence (the extent to which a participant understands the intervention and how it works and also the engagement with the programme) and experiences of taking part (including perceptions of the intervention, barriers, satisfaction).[38] The acceptability of the programme to the Osteopaths will be explored through a Focus Group.

The data collected through one-to-one interviews (see table 3) will be transcribed verbatim and uploaded into NVivo 10. Thematic analysis (one of the most widely used qualitative approach) will be the preferred method for data analysis. This method allows identifying, analysing and reporting patterns within the data.[39] Furthermore, it can be used as an essentialist method that reports experiences, meanings and the reality of participants, which fits well with the aim of this study (assessing feasibility and acceptability). Two researchers from the supervisory team will validate the analysis. The same process will be adopted for the analysis of the focus group data.

Quantitative evaluation

Preliminary data will be collected on outcomes such as depression and anxiety, acceptance of pain, mindfulness, fear avoidance and quality of life. Descriptive statistics (means, SD) will provide some insight into population characteristics and also an indication of potential changes in mean scores between the four time points (preintervention, postintervention and two follow-ups). Within-subjects effects will also be reported (F, df, effect sizes, CI, p values) and presented in a table.

[vii] 'Acceptability is a multifaceted construct that reflects the extent to which people delivering and receiving a healthcare intervention consider it to be appropriate, based on anticipated or experienced cognitive and emotional responses to the intervention.'[38]

Expected outcomes

In this feasibility and acceptability trial, we shall determine the feasibility of recruiting patients living with persistent pain to a brief ACT-based psychosocial intervention. This will include determining recruitment and retention rates, testing the procedures and exploring the acceptability of the programme as well as investigating potential changes in anxiety, depression, mindfulness, fear avoidance and quality of life. This study is in line with the MRC guidance for developing complex interventions (testing procedures, estimating recruitment, retention, determining sample size).

Although we cannot at this point test the effectiveness of 'A Mindful Act', in a full scale randomised controlled trial, we will learn whether it is feasible and acceptable to people living with long-term pain and psychological comorbidities from Southwest Wales. The quantitative data will provide an initial understanding of the potential benefits of the ACT-based programme for this particular group. The data from the qualitative interviews will increase our understanding of the experience of taking part in the intervention. Furthermore, we will have a better knowledge of the barriers to taking part and reasons for discontinuation and also an increased knowledge of the elements that are most valued by the participants.

It is expected that the participants who will engage with the activities, fill in the workbook and implement what they learnt in their daily lives will get some benefit. This model starts from the premise that by accepting and learning to live with pain, one can reduce the control it exerts over their lives. This intervention will guide individuals to change their focus from trying to eliminate pain to living as well as possible with pain. Through experiential exercises and metaphors, people will learn the futility of trying to control pain and the benefits of acceptance strategies. Participants will be encouraged to explore their values and set goals consistent with those values in order to improve their quality of life. It is expected that the participants will learn some useful

skills and feel that they have made a useful contribution to the research area.

The results will indicate the feasibility and acceptability of the intervention. The findings of the feasibility study will help enhance the intervention by making appropriate modifications to the processes and procedures involved. A larger scale study is envisaged to follow, in order to investigate the full effectiveness and cost-effectiveness of the programme.

Ethics and dissemination

The committee has approved the proposal as well as related information sheets and consent forms summarising the research. The participants will be informed about confidentiality and will agree to keep anything said within the therapeutic environment confidential and not repeat it outside it. All the project data and materials sent for publication will be anonymised by removing statements identifying participants. The data will be stored securely in a password-protected computer accessible only to the research team. The anonymised findings will be included in the first author's doctoral thesis as well as being disseminated through peer-reviewed academic journals, national and international conferences and public events.

DISCUSSION

'A Mindful Act' is an innovative psychosocial intervention for persistent pain to be carried out in a unique setting and fostering an interdisciplinary collaboration between Osteopathy and Psychology. This pairing may optimise the existing psychological benefits associated with manipulative therapies.[40] A future trial will aim to integrate ACT with Osteopathy and have Osteopaths trained to deliver an ACT-based programme for people living with persistent pain.

Another strength of this programme is brevity. Many of the people living with persistent pain do not have the physical or mental resources to engage in intensive programmes; therefore, a brief intervention is well suited for this particular population. Some of the common barriers identified in the literature such as scheduling, travel distance, high cost of treatment and out-of-pocket costs have been considered when designing the intervention (the programme is offered for free, the location is considered easily reachable by public transport and travel expenses are expected to be low, the schedule will be designed in a way to facilitate attendance).[41]

In addition, 'A Mindful Act' will actively promote pain self-management. This will be done by equipping participants with a set of knowledge and skills (eg, learning how to embed mindfulness in daily activities or identifying personal values and learning how to set realistic goals in line with their values) that they can apply in an autonomous and flexible manner, in order to live a more fulfilling and meaningful life. The participants will be encouraged to take more responsibility for their own well-being and engage in self-care activities that may help improve their quality of life (balancing exercise and relaxation, pacing, adopting a balanced nutrition, developing better sleep habits).

A major barrier of implementing interventions is the necessity of trained specialists (and virtually increased costs). However, there is research suggesting that non-primary care health practitioners (such as osteopaths, chiropractors and physiotherapists) may be ideally positioned to provide self-management and psychological support for people with persistent pain.[42] Both facilitators posses the necessary knowledge and skills in order to deliver an ACT-based intervention, which contributes to minimising the costs related to training specialist staff. In addition, this collaboration might yield insights in regards to novel ways to support and empower people living with persistent pain.

Finally, the results of feasibility study may provide valuable information useful in carrying out a full-scale trial and conducting a process evaluation to clarify causal mechanisms and to better understand the process of change. In addition, future trials may benefit from including measures of pain and functioning. An economic evaluation will also be included to assess the cost effectiveness of the intervention and to ensure that the cost of the study is justified by the potential benefit.

It is essential to acknowledge some of the limitations. First, due to the nature of this study, it will not be possible to randomise participants. In addition, the conclusions will be limited due to the small number of participants and the lack of a control group. In addition, running more than one group would have been a better test of feasibility; however, it was not possible due to time and resource requirements.

However, this is merely a feasibility study and not a full-scale randomised controlled trial. The MRC framework emphasises the importance of preparatory work to assess the feasibility and acceptability of complex health interventions prior to embarking on a full-scale evaluation. Assessing feasibility and acceptability is a crucial in uncovering potential issues related to acceptability, compliance, recruitment, retention and delivery of the intervention. Another limitation arises from the fact that this specific population is heterogeneous; people with persistent pain have different coping styles and different levels of psychosocial and functional impairment.[43]

Last but not least, the fact that the facilitators of the intervention will also be interviewing the participants about their experiences of taking part might be a source of bias. This will be addressed by having an external person carry out the qualitative data collection.

Collaborators Craig Toutt, Director of Academic and Clinical Operations (Health and Well-being) Health & Well Being Academy, Swansea University, Singleton Park, Swansea SA2 8PP, Wales, UK. Email: c.r.toutt@swansea.ac.uk. Tel: +44 (0)1792 602875.

Contributors MS designed and operationalised the majority of the protocol, wrote the majority of the paper as well as edited the final draft. JR, DJE and HD all contributed in helping MS with the design of the protocol as well as drafting the paper.

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Competing interests None declared.

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