Reference: 2020HCSREC04

N.B. please note that the discrepancy in date highlighted in my previous submission is related to the fact that, whilst we initially on 21 February 2019 (I have amended the date to this), then again in August 2019 for simplification. However, the study was submitted to the Ethics Research board for amendments again on 24/05/2022 (this was the date initially submitted as was the final submission for the currently approved document) because operationally and due to covid we have had to delay the start of the study and change to online provision (hence why I initially entered this date), for their meeting on 26/05/2022 and their confirmation of approval on 30/05/2022 (email evidence included below)

Title: *Differential contributions of stress and pain-explicit mindfulness treatment groups to processes, patient experience and outcomes in chronic pain. A randomized controlled trial and qualitative analysis*

From: HCS Research Ethics Committee <HCSResearchEthicsCommittee@gov.je>
Sent: 30 May 2022 13:48
To: Alessio Agostinis <A.Agostinis@health.gov.je>
Cc: Julia Morris <julia.morris@health.gov.je>; Jonathan Bond <J.Bond2@health.gov.je>; Moyra Journeaux <m.journeaux@health.gov.je>
Subject: RE: minor/major amendments for Committee's attention Ref: 2020HCSREC04 AA

Hello Alessio,

Following the HCS REC meeting on Thursday 26 May , I am pleased to inform you that your amendment to the study:

Reference: 2020HCSREC04

Title: *Differential contributions of stress and pain-explicit mindfulness treatment groups to processes, patient experience and outcomes in chronic pain. A randomized controlled trial and qualitative analysis*

Was noted with no ethical issues.

Please keep this email as a record of the HCS REC confirmation that there are no ethical issues.

Many thanks,
Aoife

Dr Aoife Journeaux | MB BCh BAO

HCS REC Administrator
E: HCSResearchEthicsCommittee@gov.je

I occasionally send work emails outside the hours of 8:30 am- 5:30pm Monday to Friday. If you do receive an email from me there is no expectation of a reply outside your normal hours.

Please note: the HCS REC Email box is checked once a week. Your email may not be responded to immediately.

From: Alessio Agostinis
Sent: 24 May 2022 14:01
To: Moyra Journeaux <m.journeaux@health.gov.je>
Cc: Julia Morris <julia.morris@health.gov.je>; Jonathan Bond <J.Bond2@health.gov.je>
Subject: minor/major amendments for Committee's attention

Dear Moyra,

We are requesting to go from face to face to online delivery. Nothing else. We have amended the Ethics form to reflect.

We decided to go online mainly due to covid at the time, but since then Breathworks also offered to have one of their teachers help us out with it (meaning half the workload and less impact on our clinic). I can't remember if I checked about it being a minor or major amendments. In any case, I cannot find a minor amendments form and can't recall if we discussed it or emailed about it, when we were considering changing.

See attached. I understand you are meeting this Thursday (for minors might be ok) and then in July. We are keen to start as we have delayed for so long and I am also in the process of moving on from my pain clinic role (in the next 12-15 months). We would most appreciate the committee's consideration of this and really sorry about being so late in submitting.

With kindest regards

Alessio

Dr Alessio Agostinis
Consultant Clinical Psychologist

Direct +44 (0)1534 444669

Government of Jersey
Pain Management Centre
Overdale Hospital
Westmount Road| St Helier |
Jersey | JE1 3LP

Application Pack
HSSD Research Ethic's Committee
Application for HSSD Research Ethical Approval

Version: January 2018

Approved By: HSSD Research Ethics Committee

Review Date: One year

Confidential

PLEASE NOTE:

Please read this form and accompanying notes before attempting to complete it in order to avoid unnecessary duplication of answers.

This form is intended to be used for HSSD research proposals:

- Proposed projects where participants are accessed via HSSD
- Proposed projects where investigator/researchers are employees of HSSD
- Proposed projects that will be sponsored by HSSD

Projects that are part of a multi-centre trial that have already received Multi-centre Research Ethics Committee (MREC) approval, **please also supply a copy of the full MREC application and approval as an appendix**

Projects that are part of an academic programme where ethical opinion will also be required from a university Research Ethics Committee (REC), **please also supply a copy of the full university Research Ethics application and approval as an appendix**

- *Please complete all sections of this from.* ***Where a section is not relevant to the proposed research project, please write "n/a" in the space provided.***

- *Cross-referencing of answers is not acceptable e.g. responses such as "refer to protocol" or "see above" must be avoided.*

- *Please see supplementary notes for applicants (at the end of this application form) for guidance on completing the research ethics application form*

- *Please note that a favourable opinion from the HSSD Research Ethics Committee does not constitute permission to carry out a research project. A favourable opinion means that the HSSD Research Ethics Committee is satisfied that ethical issues in planning the research project have been addressed to the satisfaction of the committee. Permission to carry out research still has to be obtained from the research site and department head.*

- *Please note that research being undertaken as part of an academic programme of study can only be granted HSSD Research Ethics approval pending a favourable opinion being granted by the university faculty REC. A record of this will need to be forwarded to the HSSD REC prior to commencing the research project in Jersey.*

Applicant's Checklist

Title of Study:	Differential contributions of stress and pain-explicit mindfulness treatment groups to processes, patient experience and outcomes in chronic pain. A randomized controlled trial and qualitative analysis
Lead researcher:	Dr Alessio Agostinis

- **This document MUST be completed and submitted as part of the application form. Please ensure ONE copy of each document, as detailed below, is attached as an appendix to this application form in the order that they appear on the list. ALL appendices MUST have dates and version numbers clearly marked.**

- **Indicate 'yes/no' as applicable, and continue your document list on a separate continuation sheet if necessary.**

Document	Enclosed?	Appendix №	Version №	Date
Applicant's Checklist (this form)	**Mandatory**			
HSSD Research Ethics application form	**Mandatory**			
List of references (APA format)	**Mandatory**	1		
Summary C.V. for lead researcher	**Mandatory**	2		
Letter(s) of invitation to participants/ Advert	**Y** ☒ **/ N** ☐	3		
Participant Information Sheet(s)	**Y** ☒ **/ N** ☐	4		
Participant and treatment provider consent form(s)	**Y** ☒ **/ N** ☐	5		
Course facilitators conent form	**Y** ☒ **/ N** ☐			
Written permission(s) from relevant personnel/organisation (eg. to use facilities and/or access participants)	**Y** ☐ **/ N** ☒	6		
Interview schedule(s) or topic guide(s)	**Y** ☐ **/ N** ☒			

Validated questionnaire(s)	**Y** ☐ **/ N** ☒			
Non-validated questionnaire(s)	**Y** ☐ **/ N** ☒			
Gannt Chart/Timeline	**Y** ☐ **/ N** ☒			
Copies of recruitment advertisement material(s)	**Y** ☐ **/ N** ☒			
Risk Assessment form(s)	**Y** ☒ **/ N** ☐	7		
Copy of CRB Certificate (if applicable)	**Y** ☒ **/ N** ☐	8		
Signature of Supevisor(s) **OR** line manager	**Y** ☒ **/ N** ☐	9		
Have you signed and dated form?	**Y** ☒ **/ N** ☐	10		
Other documents *(Please specify below, as necessary)*	**Y** ☐ **/ N** ☒			
	Y ☐ **/ N** ☐			
	Y ☐ **/ N** ☐			
	Y ☐ **/ N** ☐			

Government of JERSEY

Health & Social Services Department

Research Ethics Committee

Application for Research Ethical opinion of a Proposed Research Study

Part 1 Applicant details

Applicant name:	Dr Alessio Agostinis			
Student or staff member?:	Staff Member			
Programme of study or staff department:	Pain Clinic			
New application:		**or Resubmission:**	**X**	(Please **X** in appropriate box)
Title of study:	Differential contributions of stress and pain-explicit mindfulness treatment groups to processes, patient experience and outcomes in chronic pain. A randomized controlled trial and qualitative analysis			
Application version:	1.1			
Date of application:	01/02/2019			
Date of REC meeting to which application is being submitted:				
	21/02/2019			

- Applicants who are intending to complete the proposed research as part of an academic programme MUST discuss their proposal with their supervisor and have it signed off before submitting the application for ethical review.

- HSSD employees (where the proposed research project is not part of an academic programme) MUST discuss their proposal with their Head of Department and have it signed off before submitting the application for ethical review.

- Once you have completed your application form, and it has been signed by you and your Supervisor/Head of Department, please submit **ONE** copy of your application and **all** appendices (as detailed on the applicant checklist) by email to: L.delaCour@health.gov.je **or** by post to: Reverend Maureen Turner, Secretary - Health & Social Services Research Ethics Committee, General Hospital, Gloucester Street, St Helier.

- Applications must be received by 4pm on the submission deadline.

I confirm that:

- The information in this application is, to the best of my knowledge, accurate and I take full responsibility for it;
- I undertake to abide by the ethical principles embodied in the good practice guidelines identified in this application;
- I will not start data collection until all relevant ethical opinions are in place including university faculty REC, IRAS, NRES, or MREC as appropriate.
- If the research is approved, I undertake to adhere, without deviation, to the study as outlined in the application;
- If I need to make any changes to the study, including to the timescale, I will inform the HSSD Research Ethics Committee before implementing any changes. Where the study is part of an academic programme, I will also seek advice from the university faculty REC;
- I am aware of my responsibility to be up-to-date and compliant with the requirements of the law and relevant guidelines relating to data security;
- I understand that personal data about me as a researcher and this application will be held by the HSSD Research Ethics Committee and that this will be managed according to the principles established in the Data Protection (Jersey) Law 2005;
- I will provide a brief end of project report to the HSSD Research Ethics Committee on the completion of my project;
- I will advise the HSSD Research Ethics Committee of any publications that are a product of the study.

Name: **Dr Alessio Agostinis**

Signed: 

Date: **07/08/2019**

- Please ensure that your academic supervisor/line manager has seen and agreed to support this proposal; they must sign this form to indicate they are happy for the proposal to be submitted. All relevant signatures must be obtained **before** submitting this application. **Failure to have all the required signatures will result in your application being returned to you**, which may delay your review.

- Applicants should note that it is their responsibility to submit their proposal in sufficient time, particularly when working to tight/strict deadlines. This includes allowing adequate time prior to submission for the supervisor/line manager to read the proposal, provide feedback, and review any amendments before agreeing to support the proposal and signing the application form overleaf.

Please note:One of the bleow must be completed before an application can be accepted

Approval from Academic Supervisor

I confirm that the applicant has discussed their research proposal with me, and that I have read and agree to support this application.

Name: **Insert supervisor's name here**

Signed:

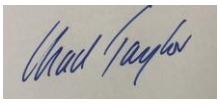
Date:

OR

Approval from Line Manager

I confirm that the applicant has discussed their research proposal with me. I understand the purpose of the research and am aware of all the implications (including time) that conducting this research may have. I am in agreement with the research and support this application.

Name: **Dr Chad Taylor, Pain Clinic Lead**

Signed: 

Date: **07/08/2019**

Application Form

Part 2: Introduction

1. Title of research project

Differential contributions of stress and pain-explicit mindfulness treatment groups to processes, patient experience and outcomes in chronic pain. A randomized controlled trial and qualitative analysis

2. Project Details

Project location:	Jersey
Project duration:	24 months
Expected start date:	July 2022
Expected end date:	April 2024

3. Lead researcher (the applicant)

NB. The lead researcher must submit a copy of their current CV (max. 2 sides of A4) with this application.

Name of applicant:	Dr Alessio Agostinis
Status: (eg.MSc student; Doctoral student; staff researcher; other – please specify)	Consultant Clinical Psychologist and Staff Researcher
Address for correspondence:	Pain Management Centre, Overdale Hospital, Westmount Road, Westmount, Jersey JE2 3LP
Contact telephone number:	01534444669
Contact email address:	a.agostinis@health.gov.je
Professional position (if applicable):	Consultant Clinica Psychologist (SOJ), Honorary Visiting Research Associate Liverpool John Moores University

Experience of research methods:	Degree in Applied Psychology (inc. research methods and analysis and qualitative thesis) Doctoral Training Qualification in Clinical Psychology (including published quantitative thesis), various audit, research posters/projects, presentation at conferences; research methods study throughout both degrees and ongoing learning.

4. Other individuals who may work on the research project

NB. If there are more than two additional researchers, please note their details on a separate sheet and append to this application. A summary CV (max. 2 sides of A4) for each additional person must accompany this application.

Name:	Dr Ben Rosser
Status: (eg. research supervisor; clinical supervisor; researcher; statistician)	Researcher Clinical Psychologist & Lecturer, Natural Sciences & Psychology, Liverpool John Moores University
Contact telephone number:	0151 904 6298
Contact email address:	B.A.Rosser@ljmu.ac.uk
Name:	Mr Jonathan Bond
Status: (eg. research supervisor; clinical supervisor; researcher; statistician)	Assistant Psychologist, Research Assistant
Contact telephone number:	0153445609
Contact email address:	J.Bond2@health.gov.je
Name:	Dr Nigel Minihane
Status: (eg. research supervisor; clinical supervisor; researcher; statistician)	Primary Care Board Lead and GP
Contact telephone number:	01534833821; 07797713081
Contact email address:	minihane@gmail.com
Name:	Colin Duff
Status: (eg. research supervisor; clinical supervisor; researcher; statistician)	Business and Research Manager, Breathworks CIC Treatment Integrity
Contact telephone number:	0161 834 1110
Contact email address:	colin.duff@breathworks.co.uk

5. Academic supervision: (if proposed research is part of an academic programme of study)	
Primary supervisor:	Type academic supervisor's name here
Email address:	Type email address here
Additional supervisor(s): **(if relevant):**	Type any other supervisors' names here
Email address:	Type email addresses here

6. Who is sponsoring the proposed research?

Eg. University, HSSD Head of Department/Consultant, pharmaceutical company, device manufacturer, charity or other organisation

Dr Chad Taylor, Pain Clinic Consultant and Lead (HCS); Breathworks Foundation has agreed to supply one teacher to provide three courses online alongisde a local teacher, to help minimise the impact on our clinical delivery We have also submitted a research grant application. The latter has since been declined.(Clulow)

If the proposed research is sponsored by a pharmaceutical company, has that company agreed to abide by:

I. The Association of the British Pharmaceutical Industry Guidance on Insurance and compensation in the event of injury in Phase 1 clinical trials 2012 (patient studies)?

☐ Yes ☐ No

II. The Association of the British Pharmaceutical Industry Guidelines for Phase 1 Clinical Trials

2012?

☐ Yes ☐ No

7. Good research practice:

Please confirm that the research will be carried out in accordance with the 4 Ethical Principles of Research – autonomy, beneficence, non-malificence and justice and in accordance with recognised standards of practice as in the Declaration of Helsinki

☒ *I agree to undertake the proposed research, as outlined in this application, in accordance with the 4 Ethical Principles of Research and the Declaration of Helsinki.*

Please state which other professional codes of conduct you will abide by (if applicable):

Type your statement of practice here

8. Will you require ethical opinion from another source?

☐ Yes ☒ No

If Yes, which other ethics committee approval do you require? i.e. university faculty REC, MREC etc.

_____

Part 3: The research

1. Type of research proposed: Please indicate whether the proposed research is:		
☐ Quantitative	☐ Qualitative	☒ Both
If other please detail:		

2. Outline of the research:

Please provide a brief outline of the proposed research under the sub-headings below.

N.B. below we included a scientic and lay person abstracts for your assistance as by way of introducing the project briefly.

200-word lay abstract

Mindfulness is a popular set of knowledge and practical techniques that can help people cope with stress. It includes meditation practices, everyday small practices to break and change usual habits, as well as understanding and developing competencies to be more aware of thoughts, emotions and physical sensations. Mindfulness can help not to excessively react to them, or becoming distressed by them.

In persistent pain (pain that lasts more than three months), mindfulness is thought to improve depression, quality of life, and even how sore people feel.

There are numerous versions of mindfulness and mindfulness-based therapies. One approach, Acceptance and Commitment Therapy (ACT), is based on science (as opposed to religion or common sense). ACT helps people to learn about and apply skills to cope with thoughts, emotions and sensations without getting upset, distracted or impeded by them. It also assists people to develop the ability to set clear goals that matter in their life. ACT evaluates successful outcomes in this areas (called 'processes') and how they link to changes in pain, mood and stress. However, more puritan mindfulness courses tend to only focus on the latter.

Research on mindfulness courses for chronic pain, can show that people improve, but not so well what changes in people's experience and skills, or how they apply these. We also know that pain sufferers who attend mindfulness courses for stress, may say it is not so relevant to their pain difficulties.

In this study we want to explore how both mindfulness for stress and mindfulness for pain courses, online, contribute to:

- how specific areas of ACT and other mindfulness learning change

If/how these link with practical skills and any emotional or improvements in the participants' quality of life, use of medication or GP visits. To help us evaluate this, we will ask participants to complete scientifically accepted questionnaires and interview them. We will then use statistical methods and qualitative methods to evaluate change.

This may help us with better supporting chronic pain sufferers with choices around mindfulness as a standalone or as part of attending intensive pain-coping programmes involving different professions.

Scientific abstract of the work proposed

In chronic (persistent) pain, mindfulness can improve coping, depression, quality of life, and reduce pain intensity. Both Acceptance and Commitment Therapy (ACT; Hayes, Strosahl et al. 1999) and mindfulness research, including Mindfulness Based Stress Reduction (MBSR, Kabat-Zinn 1982) and Mindfulness Based Cognitive Therapy (MBCT, Segal, Williams et al. 2002) provide theoretical and/or practical frameworks for *mindful* process measurement.

However, numerous methodological and contextual limitations exist within the context of pain management centres that are increasingly providing mindfulness based interventions to pain sufferers. This has potential implications for whether implementing mindfulness skills is done with clarity, good governance about whether, where and how it is helpful, or whether it even can be harmful, duplicate other treatments or unnecessarily burden pain sufferers with something that is not needed. In this context, it also has significant implications on any required development of teachers' competencies.

No current research has attempted to unify ACT and other mindfulness process measurement (how people get to change – as opposed to what change they achieve) or to establish the potential contribution and relevance of different specific mindfulness courses in chronic pain patients' treatment pathways and outcomes.

A community-based multidisciplinary-pain-management naïve sample (N=100) of chronic pain patients will be recruited in primary care and placed on a time-set waiting list and then randomly allocated to ***one*** of two standardised active online mindfulness treatments - stress **or** pain group

conditions. Measurement will include theoretically validated process and outcome measurement. Treatment adherence and fidelity will be independently evaluated from recorded sessions and inter-rater agreement checks performed.

Quantitative analysis will be performed to include descriptive statistics, analysis of variance, session-by-session process change trends, and post-hoc analysis on GP and A&E visits.

Qualitative thematic analysis will complement and bolster the findings of the quantitative phase to include additional process variables unaccounted for by the ACT model, patient experience and descriptive comparison of the two active conditions, including descriptive statistics comparing frequency of reported themes between the two treatments.

i. Aims and objectives:

This study aims to explore and better understand the contribution of standardised group-based mindfulness courses to theoretically valid and coherent mindful-change processes.
OBJECTIVES

1. To explore the differential contribution of standardised stress and pain-explicit group-based mindfulness courses on mindful-change process as described in the Acceptance and Commitment Therapy (ACT) psychological flexibility model (Hayes, Strosahl et al. 1999) on a chronic pain population that is naïve to multidisciplinary pain treatment.
2. To improve on methodological and confounding issues inherent in current research on mindfulness for chronic pain.
3. To contribute to the understanding of the potential relevance and role of standardised stress and pain explicit mindfulness courses in chronic pain treatment outcomes and pathways.

a. Hypotheses and/or research question(s) to be addressed:

Quantitative project

What is the differential contribution of online stress and pain explicit mindfulness courses to mindful-change process variables and outcomes? More specifically:

What individual contribution do mindfulness for stress (MfS; Hennessy 2017) and Mindfulness for Health – Mindfulness Based Pain Management (MfH-MBPM; Burch and Penman 2013) courses make to Acceptance and Commitment Therapy (ACT) processes and relevant chronic pain outcomes in pain-management-naïve chronic pain sufferers?

Which associations exist between weekly course content and specific process change?

Qualitative project

Given consideration of:

a) The practical impossibility of quantitatively measuring all the relevant process variables,

b) The potential questionnaire burden, and

c) The sheer number of processes and mechanisms contained within both ACT and chronic pain literature on mindfulness courses and meditation,

we aim to utilise thematic analysis to complement the quantitative findings. This will allows us to explore the impact of both versions of courses, reduce questionnaire burden in the quantitative analysis, and contribute to answering the following questions.

a) Which relevant ACT-process variables are reported by participants and how have they changed?

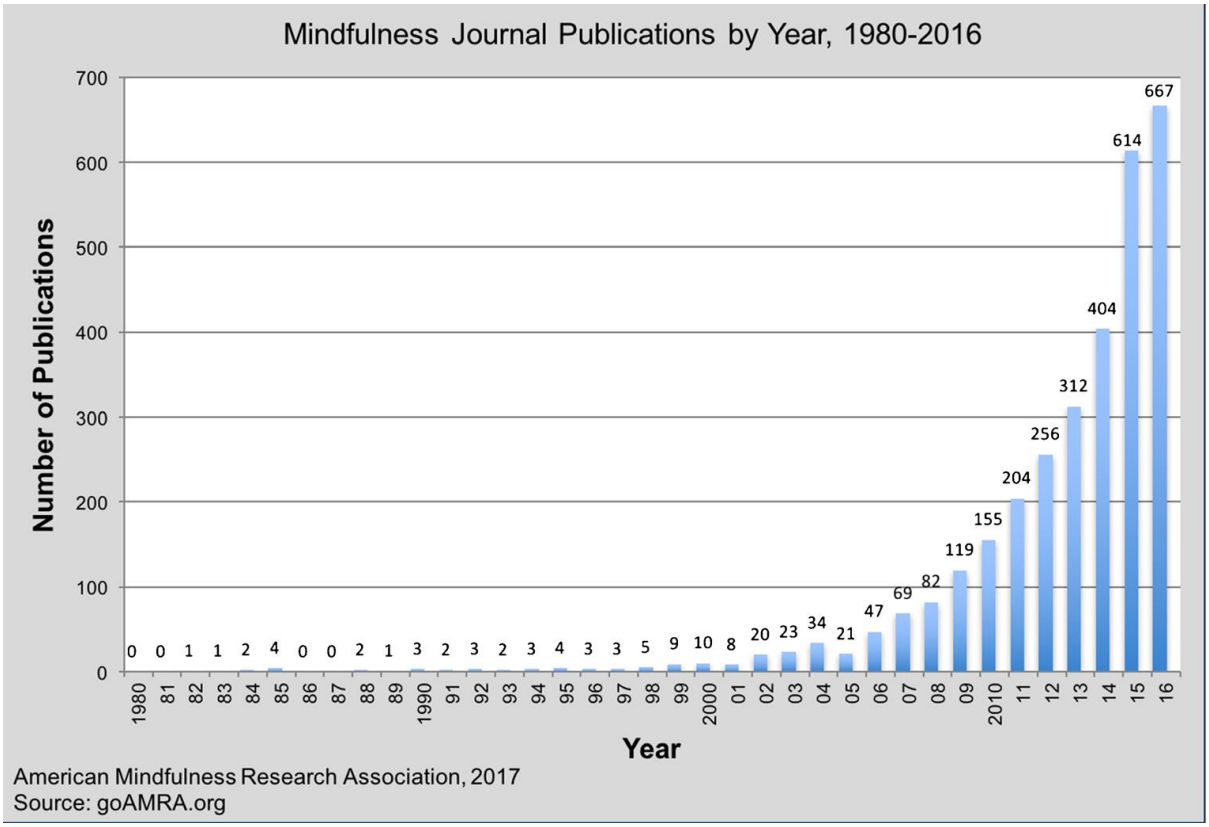
b) Do participants report the presence of other contributing variables considered within the mindfulness-groups literature in chronic pain, such as group cohesion, engagement and the impact of teachers' experience on reported change?

c) How frequently are these variables reported across the two groups, and in which direction? (improvement/deterioration/no change). This component will take the form of descriptive statistics and qualitative comparison of occurrence within patients' interview-derived themes.

ii. Rationale, to include a *brief* synopsis of the background to the research:

Mindfulness can be defined operationally as *Paying attention; on purpose in the present moment* and *non-judgmentally (Kabat-Zinn 2013)*

Evidence-based (often referred to as 'secular') mindfulness has seen an exponentially increasing interest in the scientific literature and the estimated number of published scientific journals has recently been reported to have grown from one single journal in 1982, to 667 scientific publications in 2016 (Kabat-Zinn 2017) and in excess of 30,000 Media Pieces in Newspapers (Van Dam, van Vugt et al. 2018)



(extract from Kabat-Zinn 2017)

However, there are unknowns around the mechanisms (the 'vehicles' of change) by which mindfulness works, and that these must be understood in order to avoid continued professional and public misinformation, poor research and ultimately, potential harm to the end user. (Van Dam, van Vugt et al. 2018).

ISSUES WITH AND IMPLICATIONS OF WHAT WE CURRENTLY DEFINE AS MINDFULNESS AND ITS APPLICATION TO CHRONIC PAIN

Within the context of the exponential growth of interest in and research of mindfulness (e.g. Kabat-Zinn 2017, Van Dam, van Vugt et al. 2018) including in the treatment of chronic pain (Bawa, Mercer et al. 2015, Hilton, Hempel et al. 2017), several factors have contributed to the consideration for the current project:

1. The integration of mindfulness based interventions in gold-standard multidisciplinary treatments for chronic pain, such as ACT (BPS 2013),

2. Researchers' calls to improve intention to treat, to better understand facets of what is understood to be mindfulness, better targetting of and a more unified approach to mindfulness-change process variables – thus aiming to reduce treatment burden.

3. There are relevant mindful mechanisms and processes specifically in chronic pain that have made a case from both the ACT and the more purist mindfulness research derived from group based interventions or meditation alone in chronic pain – and that are not currently typically or routinetly included in mindfulness groups research for chronic pain.

4. Methodological issues including

    a. lack of clarity about providers' competencies and requirements in chronic pain,

    b. arbitrary removal of essential components of a given intervention,

    c. often no active or waiting list control condition and

    d. no consideration at all of utilising a theoretically valid and coherent process-measurement frameworks nor consideration for the teachers' competencies requirements when delivering mindfulness courses to chronic pain patients

(e.g. Dobkin 2008, Day, Jensen et al. 2014, Van Dam, Hobkirk et al. 2014, Day 2017, Harrison, Scott et al. 2017, Hilton, Hempel et al. 2017).

From reviewing the evidence quoted, the research on mindfulness for chronic pain has exclusively utilised standardised mindfulness groups typically aimed at stress populations, excluded less researched pain explicit (contextually relevant to pain) mindfulness group interventions, ignored theoretically valid mindful-process measurement provided by the ACT framework, or not controlled appropriately for significant counfouding factors.

This debate is increasingly important considering that recently published audit data suggets that

mindfulness in one format or the other, or as part of ACT-based multidisciplinary treatment is being provided regularly in pain management centres in the UK . This has been leading, possibly premautrely, to discussion about providing training in mindfulness competencies for pain practitioners such as mindfulness enquiry or leading meditations (e.g. Williams, Watson et al. 2017), which may lead, in turn, to implementing professional skills without sound, targetted and theoretically evidenced rationale.

METHODOLOGICAL ISSUES WITH CURRENT MINDFULNESS RESEARCH AND THE IMPROVEMENTS WITH THIS STUDY

The current research will therefore aim to address and control, some of the currently reported methodological issues in research on group mindfulness based interventions (MBIs), including:

- Utilising a waiting list for the whole group as a control prior to randomisation. This will act as a pseudo treatment-as-usual condition and will track key outcome and process measures across this time.
- Utilising two active interventions, Mfs and MfH-MBPM, with standardised, transparent, comparable in content, time and delivery process that can therefore be easily evaluated for adherence and treatment fidelity.
- Using established and matched teacher's competence in line with UK Network standards (MBTT 2011)for the intervention delivered.
- Utilising the same 'dosage' and type of interventions (groups with similar structure, delivery times and requirements for practice) utilising MfH-MBPM and MfS (Burch and Penman 2013, Hennessy 2017)
- Using appropriate psychometric and qualitative analysis and targetting of explicit process-change.
- Reporting adverse side effects
- Measures in line with IMMPACT recommendations for research on chronic pain (Dworking *et al.*, 2005).

iii. Study design, to include recruitment and sampling strategy, inclusion/exclusion criteria, sample size and justification:

In order to address the research questions, the current study will be divided in and presented as separate quantitative and qualitative components:

Quantitative study:

Design and Method

DESIGN

A waiting-list controlled, randomised, pilot trial of mindfulness based group treatment comparing two active standardised interventions (mindfulness for stress vs. mindfulness for pain/health)

SETTING AND STUDY POPULATION

An opportunity sample via general practice, waiting-room advert and GP supported recruitment in Jersey, serving a population of 106,000, will be invited to take part in the study.

RECRUITMENT

All general practices in Jersey will be invited to take part in this study. They will be recruited through the Jersey Primary Care Body and Social Media Advertising.

CASE IDENTIFICATION

Over a six months period.

Once potential participants have consented, searches will be run on GP electronic health records to identify suitability. Demographic data including gender, age, ethnicity and employment status, pain diagnoses, current medication and dosage, co-morbidities and mental health diagnoses will be extracted via GP referral to the study, including that the patients meet inclusion criteria and do not meet any of the exclusions.

INCLUSION AND EXCLUSION CRITERIA (PATIENTS)

Inclusion criteria:

1. Pain > 3 months
2. Ability to communicate and literacy in English
3. Age 18 years or older
4. No current outstanding medical tests or procedures for conditions expected by the GP to interfere with participation in treatment.
5. Has not previously received non-medical treatment at a specialist pain centre, or

attended a multidisciplinary pain management programme.

6. Ability to utilise online video conferencing technology (i.e. ownership of a compatible device & necessary technical competence)

Exclusion criteria:

7. Patients who are actively suicidal, terminally ill or have dementia, cognitive impairment, learning difficulties, or the GP knows of another reason to exclude.

ETHICAL ISSUES

Informed consent

We will obtain approval to contact practices regarding the study with participant's information leaflet and GP information leaflet. We will also obtain informed consent from the treatment providers, including in relation to video/audio feed being recorded. Participants will be offered opportunity to switch off their cameras.

Confidentiality

Data will not be accessed outside the research team. Once collected, checked for inclusion criteria and allocated to a randomly generated participant number, data will be anonymised and prior to the off-site transfer for blind analysis (the statistician will not be aware of which condition stress/pain the participants have been allocated to). Data Transfer Protocols will be utilised in line with the Government of Jersey Governance and Data Protection system, to transfer the data ahead of analysis.

A participant waiting-list randomised, pilot trial of mindfulness based group treatment comparing two active interventions (stress vs pain mindfulness courses) and the waiting-list at recruitment time and 8-weeks post recruitment, coinciding with the start of treatment.

Randomisation will be based on computer-generated random numbers and the sample randomised, will act as a pseudo-waiting-list control for the eight-week waiting period ahead of the intervention.

Recruitment details and Participants

PARTICIPANTS AND DATA COLLECTION

100 people with chronic pain (defined as > three months duration) will be recruited from primary care and social media adverts in Jersey (the social media participants will be

required to register their interest via their GP who will then refer to the lead researcher). Once recruited, participants will be required to complete baseline outcome and process measures, 8-weeks ahead of beginning their 8-week course. Randomisation will take place at this point to either the stress or the pain course. They will repeat this assessment on week 1 of the course and then again at week 4. They will also complete only process measures weekly during the course, in order to explore for links between weekly course content and specific process change.
Posttreatment assessment will be completed within four weeks of treamtent completion and at 3-month follow up.

How this study will improve on previous research

The current study therefore offers an opportunity to impact on the understanding, application of mindfulness and management of chronic pain in the following ways:

- Improved targeting of mindfulness courses as part of multidisciiplinary treatment for chronic pain
- A better understanding of the contribution that mindfulness courses may provide in chronic pain patient treatment pathways, as improved understanding of their mindful-process-change relevance, may allow improved targetting and avoid unecessary duplication, treatment burden or even harm.
- Improving the understanding of the requirement for and development of relevant teaching/training competencies in mindfulness in this area.
- Potentially contributing to establishing whether full mindfulness courses have a place (and what that is) building up to, or as part of multidisciplinary pain management programmes or possibly ahead of these, within the community or as an adjunct to them- for chornic pain sufferers.

Procedure:
100 people with chronic pain (defined as > three months duration) will be recruited from primary care and social media adverts in Jersey (the social media participants will be required to register their interest via their GP). The allocation (stress or pain) will not be concealed from the participants, treatment providers or the researcher. However, analysis of the data ill be conducted blind to allocation. Post-treatment assessment will be completed within four week of

treamtent completion and at 3-month follow up. The sample size has been determined to recruit 8-12 participants for each of four stress and pain courses to be administered with a recruitment of 50 and a minimum target of 30 per active intervention.

Qualitative study:

DESIGN AND SETTING

A qualitative study involving semi-structured interviews will be held, with a topic guide informed by the ACT psychological flexibility model (Hayes, Strosahl et al. 1999) and Day's framework for mindfulness-relevant processes (Day, Jensen et al. 2014)in chronic pain, and based on mindfulness research improvement based on adaptations of Mindfulness Based Cognitive Therapy (MBCT) for chronic pain (Day 2017).

Exclusion criteria (in addition to quantitative study criteria):
Non-completers (participants who completed less than 6/8 course sessions)
Declined to take part in interviews

SAMPLING

An opportunity sample from all patients invited to take part to the quantiative research aspect, invited as part of the intial quantitative study informed consent process.
We will invite all participants from the sample, aiming from 10-15 participants from each the stress and pain version of the courses, hence a total sample of 30 participants maximum and a target of 10 completed interviews for each intervention.

iv. Proposed method(s) of data analysis

Quantitative:

PRELIMINARY ANALYSIS

After randomisation, we will carry out preliminary baseline analysis using independent group t-tests to establish no signifcant demographic (age, education, duration of pain, number of comorbid medical conditions, visits for pain the past three months) or psychometric differences between the groups. This will act as a pseudo-waiting list treatment-as-usual (TAU) control group.

MAIN ANALYSIS

Treatment process change and outcomes

Means, Standard Deviations (SDs), between-group analysis of variance and co-variance (ANOVA, Between-Group ANCOVA) results and effect sizes (Between-Group effect sizes: d) for pretreatment, session-by session process change tracking including a practical selection of accepted and validated process-change measurement for all six areas of psychological flexibility and outcome measurement related to:

- pain intensity and interference
- impact on functioning
- emotional functioning (depression, pain catastrohpizing)
- Global impression of functioning

for baseline, half-way, end-of-treatment and follow up

Analysis will be performed utilising SPSS.

These will include a practical selection of primary outcome measures, treatment process measures, as well as measures of emotional functioning, patient rating of change and change in medication use.

Post-hoc analysis

Will include number of GP and A&E visits comparing the waiting period and from the end of treatment to follow up.

STATISTICAL POWER

This study will be a modification of a previous pilot test trial of a brief, *widely inclusive* UK primary care setting (McCracken, Sato and Taylor, 2013), to include the whole sample of participants acting as a waiting list control, randomly allocated to two active treatment conditions. In line with this study which was delivered in a population area of 119,000 people, power calculations were not completed, nor were formal predictions of signficant treatment effects. This was on the basis that the same treatment format and in a community based sample had not been tried before and demonstrated of successful rectuirment of > 60 participants within a two-month period and reporting moderate effect sizes for the active condition. Given the whole island population of Jersey is estimated currently at 106,000, power calculations will not be provided in this study as the sample size was deemed appropriate in the previous that also cited

a number of studies with similar sample sizes and obtained from populations greater than Jersey.

PROCESS AND OUTCOME MEASURES

Process and outcome measurement has included consideration of factors such participants' burden, requirement for validated ACT and mindfulness groups process measurement (Day, Jensen et al. 2014, Day 2017, Feliu-Soler, Montesinos et al. 2018), relevant recommendations on measurement of outcome in chronic pain (Dworkin, Turk et al. 2005) and our current research team resources.

Ultimately, in attempting to have a clearly targeted study, we have been unable to have comprehensive quantitative measurement and the qualitative analysis will go some way to compensate for that.

Process measures:

In line with a recent review of validated and acceptable measures of psychological flexibility in chronic pain (Feliu-Soler, Montesinos et al. 2018) :

1) *Acceptance*
    a. The 7-item Acceptance and Action Questionnaire v.2 (AAQ-II, Bond *et.al*, 2011) will be utilised to measure the person's change in willingness to experience general unpleasant feelings and emotions that are not pain related (not to unfairly disadvantage the stress version of the course)
    b. *Pain Acceptance* The 8-item Chronic Pain Acceptance Questionnaire (Fish, McGuire et al. 2010)
2) *Contact with the Present Moment:* The Mindful Attention Awareness Scale (Brown and Ryan 2003) will be utilised.
3) *Self in context*: The Self Experience Questionnaire (Yu, McCracken et al. 2016)(SEQ, Yu, McCracken & Norton, 2016) will be utlised.
4) *Cognitive fusion:* the Cognitive Fusion Questionnaire (Gillander *et. al*, 2014)
5) *Values:* The Chronic Pain Values Inventory (McCracken and Yang 2006)
6) *Committed Action:* The 8-item Committed Action Questionnaire (McCracken, Chilcot et al. 2015)

Outcome measures:

Pain Intensity and interference on quality of life : the Brief Pain Inventory – Short Form (Tan, Jensen et al. 2004), numeric rating scale (NRS) on intensity (scale 0-10) including, worst, least

average (in the past week) and right now. BPI interference scale for impact on quality of life.
Emotional Functioning

a. *Pain related distress:* The Pain Catastrophizing Scale (Sullivan, Bishop et al. 1995)

b. *Depression:* The Beck Depression Inventory – Fast Screen (Poole, Bramwell et al. 2009)

Global Impression of Functioning: the Patient's Global Impression of Change (Guy 1976)will allow to consider perceived improvement and deterioration.

Qualitative:

DATA ANALYSIS
Transcribed data will be managed with NVivo software. All transcripts will be read and reread to ensure familiarity with the data. We will use thematic analysis(Braun and Clarke 2006) to identify recurring themes across the data and examine relationships between themes. The thematic analysis will be undertaken by two researchers independently coding for emerging themes and then comparing codes and themes.

TOPIC GUIDE
Do you have any previous experience in taking part in clinical trials or medical research?
I'm really interested in finding out what were your initial expectations and feelings about the mindfulness course?
What do you feel you have gained from attending the course?
What (if any) changes have you noticed in your health/quality of life? [probe for anything getting better or worse: health, emotional, physical, practical]
How do you feel the course has contributed to how you manage chronic pain?
This study has involved you doing some reading, meditation and practices in everyday life ('habit releasers'). Would you give me a sense as to whether you have managed to engage in these practices? [Ask about how long typically they have practiced daily formal meditation; are they still practising?; What has stuck and what hasn't?]
Is there anything else you would like to say about your experience of the course?
How do you feel the teacher contributed to your experience of the course?
What contribution do you feel the group has made to what you have learnt?

Since attending the course:

- Can you tell me if you have noticed any changes in pain?

- Have you started or stopped any other treatments for your pain? [what and why] (prompt re prescribed and other treatments e.g. CBT/diet/complementary medicines/cannabis)
- What have you noticed about your thoughts? [prompt re whether they notice their thoughts more or less in the past and future and whether they can bring themselves back to the present more or less – and how do they achieve that?]
- What would you say the course has contributed to how you respond to thoughts and emotions?
- How has the course contributed to how you respond to pain within yourself and in what you do or don't do?
- What changes you have noticed in how you manage or experience bad days with pain?
- How has the course influenced what you see is important to you in life?
- What have you noticed in terms of whether you do or do not see important things through ? [prompt if needed: do you notice whether you avoid important stuff has changed in any way? If 'yes', how?]
- How do thoughts and feelings shape you as a person and in life?

General prompts to be used flexibly include: What was that like? Can you give me an example of that? How did you feel about that?

v. Description of site(s) / facilities required:

The study (delivery of courses and interviews) will take place online.

Given the expected sample size (approximately 50 per active condition) for the quantitative project, it is likely there will be a requirement to run three courses twice per week (two stress and two pain) over eight weeks. This will be done around the current pain clinic requirements and At coordinated and pre-agreed times.

3. Ethical issues:

Please summarise what you think are the ethical issues inherent in this study. The

questions that follow will give you the opportunity to demonstrate how you will manage these issues in the conduct of your research.

Potential to cause distress

There is a chance that patients may become upset talking about chronic pain, related or unrelated emotional difficulties and there may be risk, during the course or the interviews. If this should occur, the participant will be given the option to stop the course/interview and be linked with the consultant clinical psychologist overseeing the project (who will be available throughout the duration of the courses for supervision) and, if required, case management and signposting to the GP or appropriate mental health services.

Also see Risk Assessment in Appendix. In addition, the lead researcher will remain as contactable throughout the project and will provide advice, risk assessment and signposting throughout the project. At the outset of each group and as part of group agreement and rules, all participants will be made aware of the need to speak to the facilitators should they experience any significant adverse physical or emotional difficulties requiring further medical or psychological attention.

i. **Are there any potential risks or adverse effects to participants?**

As well as any physical risks or adverse effects, you should consider the potential for discomfort, distress, inconvenience or change in lifestyle for the participants, and explain how these will be managed.

See Risk Assessment

ii. **Are there any particular requirements or abstensions that will be imposed on participants?** *(Eg. multiple attendance sessions; abstention from alcohol, tobacco, etc.).*

Participants will be required to attend all 8 sessions of the mindfulness course and will be classed as completers with a minimum of 6 sessions.

Participants will be required to abstain from alcohol, illegal or otherwise mentally impairing substances.

Participants will be required to keep a log of their personal-time practice, read the appropriate course manual/book and complete their home mindfulness practice.

iii. Are there any potential benefits to participants, or to the wider society?

Given the evidence presented earlier and the broader evidence of mindfulness, the current costs of attending mindfulness courses, participants will be able to complete a full and Breathworks accredited Stress or Pain Course, which also provides the basis for future mindfulnes teacher training in line with current UK standards. These courses would usually retail in the region of £190-£350 per head.
As the courses will be offered to a community sample, this will not prevent patients with chronic pain from accessing the current provision at the local pain management centre. In actual fact, it will give opportunity to more people to access both stress and pain coruses.

Above and beyond the benefits to understanding research, they will contribute to furthering understanding, improving provision of pain specialist services and to pain professionals competency standards.

The benefits of mindfulness go beyond pain and include those to the workplace, team working, productivity, stress and performance and general wellbeing.

iv. Are there any potential risks or adverse effects to *researchers themselves*?

Given the open recruitment via social media, there is the potential risk of unknown participants' forensic or problematic history. However, this will be mitigated by requesting all participants seek to access the research project via initial contact with their GP surgeries.

v. Where samples will be taken from the participant, please state which samples, the amount and frequency of them and whether the sample would be taken as part of the normal patient care or specifically for the purposes of the research? If a sample would normally be taken as part of usual patient care - will the amount taken be any greater due to the participation of the participant in the research?

Not applicable

vi. Where the research involves the use of radioactive isotopes, please confirm that the dosage proposed to be used in the research has been approved by a Radiological Safety Committee or Administration of Radioactive Substances

Advisory Committee (ARSAC), and that the person(s) who will administer the dose is/are properly qualified and hold(s) the necessary certificate(s)?

Not applicable.

vii. **Where the research involves the testing of a medicinal product (or medical device), please state the regulatory status of the drug/device in question. Is the research being conducted under the terms of a product licence, Clinical Trials Certificate (CTC), Clinical Trials Exemption (CTX) or Doctor's and Dentist's Exemption (DDX)?**

Not applicable.

viii. **Please indicate whether participants will receive payment or reimbursement for taking part in the research study** *(including reimbursement of expenses).* **If so, what amount?**

Not applicable.

ix. **Please state the relationship, if any, which may/will exist between the researcher(s) and potential participants.** *(Eg. will any of the participants be students, subordinates or colleagues of the investigator, or staff members of the University?)*

Not applicable. However, given the nature of Jersey, participants may be known to the research team, may be acquaintances or fellow colleagues. This is unavoidable.

4. Informed consent:

Will informed consent be obtained from the research participants?

☒ Yes ☐ No

If 'YES', please give details of who will obtain consent and how this will be done, including how long participants will have to decide whether or not to take part. If 'NO', please explain why not.

Participants will be initially approached with support of GP practices and local social media pages for working age adults (18 yrs and above), given that chronic pain speciality in children and young adults is a specialty within itself.

Potential participants will have two weeks to contact the researchers for questions and to consider opting-in.

Children

Can you confirm that, where the participant is 16 years old or over, consent to participate in the research will be obtained from the young person themselves.

☒ Yes (but not applicable in this project) ☐ No

Can you confirm that, where the participant is under 16 years of age but is judged to have the maturity and capacity to understand the nature of the research, consent to participate in the research will be obtained from the young person themselves.

Not applicable.

Please state the manner in which any apparent objection to participation by a minor will be handled.

Not applicable.

Please state whether and how parental consent, or consent of the legal guardian or order/declaration of the court, will be sought in relation to the participation of minors.

Not applicable.

*NB. Copies of the consent form(s) and Participant Information Sheet(s) to be used in the research **must** accompany this application.*

5. How will participants who may not adequately understand verbal explanations or written information given in English be enabled to consent?

Not applicable. Given the resource for this project, the potential confounding effects to the wider group and the manner in which groups are delivered, it will be a requirement for potentail participants to be able to understand verbal, written explanations and in English.

6. **Please state what measures will be taken to ensure that participants are able to withdraw from the research at any time without explanation and without fear of reprisal should they so wish**

   This will be included in the consent form.

7. **Confidentiality of data:**

   What measures will be taken to protect the confidentiality of participants' data?
   You should consider data in hard copy, electronic and audio/audio-visual form. You should explain how the anonymity of participants is protected during the data collection process, during data analysis and at the end of the research project.

   All participants will be allocated a participants number/code to protect their identity and databases will be anonymised, once paper/online survey data is submitted by the participant. The data will be anonymised before being shared with the university statistician.

   All data will be stored/shared within SOJ or appropriately encrypted USB storage devices and University

   Who will have control and act as custodian of the data used in / generated by the research?

   The lead researcher.

   Can you confirm that the data will be retained in accordance with the Data Protection (Jersey) Law 2005 which states that "data shall not be kept for longer than is necessary"?

   ☒ *Yes, I confirm that data, with regard to computer storage and processing of participants' personal information, will be stored securely and confidentially for no longer than is necessary and comply with the Data Protections (Jersey) Law 2005. As far as possible, the data supplied and generated during the course of the study will remain confidential.*

8. **Vulnerable groups:**

Are you *specifically recruiting* participants from any of the following groups?

Children under 16	☐
Pregnant women	☐
The elderly	☐
Persons suffering from mental disorder	☐
Adults with learning disabilities	☐
Prisoners	☐
Young offenders	☐
Other vulnerable groups	☐

Please explain why it is necessary to conduct research involving such participants, and whether the required data could be obtained by any other means.

Not applicable

Please state what special or additional arrangements, if any, will be applied, particularly in relation to Participant Information Sheets and gaining informed consent, to safeguard the interests of such participants.

Not applicable

Please state whether, and if so, how participation in the proposed research may/will be of personal benefit to individual participants.

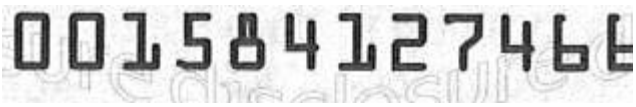
As above

9. Disclosure statement:

If you are working with vulnerable adults or minors (under the age of 18 years old), please state whether or not you have applied for and/or received a disclosure statement from the Criminal Records Bureau (CRB).

☒ Yes ☐ No

If 'YES', please give the disclosure number and date this was made.

Disclosure (certificate) number:	
Date of disclosure:	14/08/2017

Part 4: Financial and other arrangements

1. **Please state any financial or other interests (including any conflicts of interest) that the applicant, supervisor(s) or employer has in relation to the conduct of this research.**

   The Lead Researcher is a Breathworks Accredited Mindfulness Teacher since 2013 and trainer since 2018. He is also an ACT practitioner and part of the Brewathworks Work Advisory Group (2018). However, given the project will evaluate the data utilsiing both Breathworks packages as active interventions, and with equal provision of both packages, there is not a direct preference for a given therapeutic approach. Breathworks have agreed to support financially the project and contribute to assessing the fidelity of the interventions provided. However, the analysis of data will be performed blind by Dr Ben Rosser at LJMU, in order to manage any potentail conflict. There is no financial incentive or reward for the applicant, supervisor or employer in conducting this research.

2. **Please state the amount of payment, if any, that will be paid to the researcher(s) *[over and above their normal salary]*.**

   None

3. **What additional costs will be incurred by HSSD through the conduct of the research, and how are these to be met? Please state the details of any funding which has been secured for the research.**

   Currently Breathworks are considering the funding of two teachers to deliver the mindfulness interventions (flights, accommodation and subsistence), estimated to be in the region of £8000 plus £8160 in travel, accommodation and subsistence costs.

   We have also applied for in the region of £13000 to cover the qualitative analysis of the

data. Failing that, we will utilise trained volunteers and support from University (*See Clulow application form).*

The pain clinic lead and project sponsor, Dr Chat Taylor, has agreed for the project to be part of the Pain Clinic research work that forms part of the lead researcher and assistant psychologist / research assistant remit, and therefore, as part of the job plan of both members of staff. It is also in line with the pain clinic strategy around contribution to teaching and training on self-managing pain in Jersey. We have however showed the monetary value of this contribution as part of any requests for support and grant requests.

Dr Taylor has agreed to fund materials (books that are used as course manuals, stationery for psychometric and interview material, floor mats, refreshments and utilisation of group room within the premises outside of the times used by the clinics regular courses). The anticipated cost of books is in the region of £1000, mats & stationary £200 & refreshments £40 Total: £1240

Stationary costs will be will be mitigated with the use of online survey tools where possible (surveymonkey).

4. **What arrangements are in place for monitoring the conduct of the research, and dealing with any issues, complaints or adverse effects which may arise from the research?**

   [Note that, in the first instance, complaints should be addressed to the Academic Research Supervisor or the sponsoring Head of Department]

   The lead researcher will be the point of contact for any adverse effects (distressing thoughts or emotions) arising from the intervention. However, to mitigate this, no participant with current diagnosis of PTSD or active psychiatric condition requiring treatment, or drugs and alcohol dependence will be accepted on the trial (part of the exclusion criteria) as part of the recruitment process.

APPENDIX

Appendix 1

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Appendix 2 CV

CV OF LEAD RESEARCHER: DR ALESSIO AGOSTINIS

I obtained my first Bachelor of Sciences with Honours Degree, in Applied Psychology, from Liverpool John Moores University in 2002. I subsequently successfully completed a Doctoral Degree in Clinical Psychology from the University of Leeds in 2008. This is a highly competitive 3-year programme including academic, clinical and research components. It terminated with successful completion (and eventual publication in the scientific literature) of a Doctoral Thesis (*The Role of Analgesia, Mood, Post-Traumatic Stress and Demographic Variables in Mimicking Post-Traumatic Amnesia*). I am a registered practitioner with the Health Professions Council (HPC reg. n PYL01708) and I have further achieved Associate Fellowship status with the British Psychological Society (BPS reg. n 096782), due to my length of membership and my service as an Executive Committee Member of the British Psychological Society (North East of England Branch) between 2006 and 2008. I feature both on the Charter and the Expert Witnesses Directories of the Society and I am a member of the Division of Clinical Psychology within the Society. I am a UK listed mindfulness teacher and accredited Breathworks mindfulness teacher and associate mindfulness trainer.

I have trained, practiced and continue to do so with adults presenting with a wide range of psychological difficulties, including anxiety, depression and Posttraumatic Stress Disorder (PTSD), as well as more complex presentations including physical and psychological co-morbidities (chronic pain). I provide assessment, psychological therapeutic interventions, teaching and training to individuals, groups, health-insurance clients and various organisations. My therapy practice is informed by Cognitive Behavioural Therapy (CBT), as well as a mindfulness-based evolution of this called Acceptance and Commitment Therapy (ACT) and EMDR, a trauma-based adaptive information processing therapy. I have provided medico legal expertise in personal injury including the range of psychological conditions and persistent (chronic) pain, since 2009. I am employed full time by the States of Jersey as the only Clinical Psychologist specialising in Chronic Pain Management. In addition I am the only Psychologist in the Channel Islands working within a multidisciplinary intensive Pain Management Programme in line to the packages offered elsewhere in the UK. As part of

ensuring that my level of expertise remains current, I have regular formal supervisory contact with my counterparts managing the largest Pain Management Centres in the UK and regular mindfulness and therapy supervision.

I further maintain my knowledge base and research skills by attending and submitting research data to National and International Conferences, which have included Montreal and Milan World Pain Congresses (2010, 2012), British Psychological society NEE Branch Conference (2013), States of Jersey Quality Improvement Awards on piloting and implementing mindfulness in the local pain service. (2016). I have been an Honorary Research Fellow of Liverpool John Moores University since December 2017.

I am the founder and principal of Jersey-based CTT International, a business offering a mixture of bespoke psychological consultation, therapy and training, as well as formal diagnostic assessments and workplace reasonable adjustments of adult dyslexia. I am also the Managing Director of Jersey International Mindfulness Centre Limited (JsyIMC) a mindfulness specialist provider to corporates and high performance athletes both in Jersey and in the UK.

A list of published conference posters, papers and presentations, as well as of delivered mindfulness workshops and teaching is available on request.

BIOS for the current research and supporting team also include:

Dr Chad Taylor (sponsor), Consultant in Pain Medicine with professional responsibility and interest in prescribing for Persistent Non-Malignant Pain (PNMP) including presenting at national pain conference (2013) on “Opioid Use, Risk Assessment Stratification and Management”

Colin Duff

(MSc Manchester University) has worked with Breathworks CIC since 2007, coming from a background in business and mindfulness teaching. His role at Breathworks includes liaising with academic and health service partners in business and research projects, as well as working with clients from a wide range of backgrounds.

Ben Rosser

Ben Rosser is a clinical psychologist working at Liverpool John Moores University as a senior lecturer/researcher. He also holds an honorary contract within the NHS, working clinically one day a week in a Clinical Health Psychology department. Ben Rosser has an interest in third-wave therapies and has used Acceptance and Commitment Therapy and mindfulness in his clinical practice. His research interests include transdiagnostic conceptions of psychological difficulties and he has recently published a systematic review on the topic of intolerance of uncertainty. Ben Rosser has completed both clinical (DClinPsy) and academic (PhD) doctorates. He completed his clinical training at the University of Exeter and PhD at the University of the West of England. His previous research experience was in chronic pain and telehealth at the University of Bath. His publication list includes a range of peer-reviewed research and reviews on these topics.

Mr Jonathan Bond

Jonathan has worked at the pain clinic as a voluntary assistant psychologist and research assistant and is currently employed as the team Assistant Psychologist. He is a psychology graduate with an aptitude for operational management who will support with the operational and data collection aspects of the project, under supervision of the project lead.

Dr Nigel Minihane

Nigel is the local Primary Care (GP) Body Lead and has numerous years experience on the strategic delivery of primary care, he still works as a GP and has been involved in supporting various projects in the past. He has kindly agreed to support us in the delivery of the current project and has been involved in a number of conferences and pain-related chronic patient initiatives in the past.

Appendix 3: Invite Letter/Advert text.

Jersey Online Mindfulness for Pain Study

Date

««AddressBlock»»

Dear

Jersey Mindfulness for Pain Study – A Request for your involvement

Do you have chronic pain? If so, this is an invite for you to take part in this important study into the effect of Mindfulness on persistent pain conditions by attending a free online mindfulness course. Please find enclosed an information sheet outlining the purpose and benefits of the study. This study is being undertaken through a collaboration between Jersey's Pain Clinic, local GPs, Breathworks CIC, a community interest company specialising in creating & providing mindfulness courses, and Liverpool John Moores University.

The study is investigating if there is a difference between Pain and stress versions of mindfulness courses as a treatment for persistent pain. The results will be used to improve the management of Persistent Pain conditions in Jersey.
(Please contact us on 01534 444669 or a.agostinis@health.gov.je for further information and if you wish to consider signing up)

It is important that a large sample of the Island's community of persistent pain sufferers take part in order to make the study valid. **All data from the study will be analysed anonymously** and your name and address are included in the first instance only, to allow administration of the questionnaire and to send reminders. **The identity of participants providing the questionnaire and interview data will be removed prior to analysis.**

The study has been scrutinised by the HCS Research Ethics Committee and granted a favourable ethical opinion. It is envisaged that the findings will be of high relevance to patients, clinicians and the Island as a whole but also the wider clinical community. The results will be disseminated to you all as they become available.

Thank you for taking the time to look at the enclosed information and deciding whether you wish to take part in the study.

Yours faithfully

Dr Alessio Agostinis
Consultant Clinical Psychologist in Pain
Lead Researcher

Appendix 4. Participant Information sheet

Online Mindfulness in chronic pain: Jersey Study

Information Leaflet

We are requesting your participation in a research study to explore how online mindfulness courses may influence your experience of pain and how you cope with it. You have been sent this information because you have been identified or self-identified as currently suffering from a persistent (chronic) pain condition. The research is led by a Pain Consultant Psychologist and the courses will be delivered by Breathworks CIC accredited mindfulness teachers. Breathworks are a UK Community Interest Company that has developed mindfulness courses for pain, stress and the workplace and they have included sufferers' own experience of mindfulness in these.

What is the purpose of the study?

Persistent Pain (PP) is a very common problem which can be managed in a variety of ways. This research will help us to better understand how different versions of mindfulness can help people with PP including pain itself, the interference caused by pain and the related emotional distress. We hope to use the information provided to develop the island's existing mindfulness provision in a way that is more targeted to people's individual needs both in the community and in specialist pain management centres.

What will the study mean for me?

If you agree to take part, you will be invited to attend an 8-week online mindfulness course (either a stress or a pain specific course) led by a qualified mindfulness practitioner for 2.5-3 hours once a week. You can attend using either your phone, laptop or tablet device using a free videoconferencing app. You'll be also invited to practice in between sessions (approximately 20 minutes each day in your own time), including meditation, keeping a short diary of your practice (and duration) and to attend all sessions. You will be given a book and a CD of guided meditations. You will be asked to fill in a questionnaire once you are deemed suitable and placed on the waiting list for the course. Then again weekly for the duration of the course and one and three months after the course. You will be asked to do so via an online survey link or paper, which will take approximately 20 minutes each time to complete. At the end of the course you may be invited to give a short confidential interview about your experience of attending the course that will last around 30 minutes but only a proportion of participants who are willing will be invited to do this interview. The mindfulness courses will be video recorded. The follow-up interviews will be recorded for the purpose of transcribing the information for qualitative analysis and only seen by members of the research team for this purpose.

All the data you provide us will be strictly confidential, it will be anonymised and the members of the research team analysing the data will be blind to the identity of individuals involved. The research will be run in conjunction with Liverpool John Moores University (statistician) and Breathworks CIC.

How will my Information be Stored?

We will use the information you provide in a manner that conforms to the Data Protection (Jersey) Law 2018. For further information about how data is used in the Pain Management Clinic, please see the Pain Management Clinic Privacy Notice. Should you wish to obtain a copy please contact the Pain MDT Coordinator on 445609

The protocol for the Mindfulness for Pain Jersey Study has been granted a favourable ethical opinion from the HCS Research Ethics Committee.

N.B. If you touch on any matter that raises a concern about the wellbeing or safeguarding of another person or yourself, we are duty bound to pass that information on to a relevant agency, which means we are unable to keep such information confidential.

You are free to withdraw your participation from the study at any time, even after you have signed the consent form. You will be able to withdraw your data from the study only ahead of the data analyses. These are expected to take place at the end of the courses and six months later when you complete the related end and follow-up questionnaire packs(for the main analysis) and within six months, for the recorded interview (if applicable to you). Should you wish to withdraw, the information you provided will be destroyed.

Do I have to take part?

Your involvement in the study is purely voluntary; you do not have to take part if you do not want to. In order for the study to be valid, we will require the participation of a large number of participants and we would therefore be very grateful for your involvement.

Are there any risks involved?

Some studies have shown that meditation can cause increased distress in people with Post Traumatic Stress Disorder, or if there is current psychiatric difficulty. If you have this condition we do not recommend you taking part in this study.

Will my taking part in this study be kept confidential?

All the information you give us will be treated in the strictest confidence and used only for the purpose of this research study. The consent form, with your name on it, will be removed from the questionnaire and the matched data sets will be anonymised prior to analysis.

Who is organising and funding the research?

The Research Team consists of clinicians from HCS (Pain Management Centre), Jersey Primary Care (GPs) and the Breathworks CIC and Liverpool John Moores University. The Jersey research team are completing the work within their usual job roles with no additional financial funding. The Breathworks Foundation are also providing funding for one of the teachers delivering the classes.

Who has reviewed the study?

The study has been scrutinised by the HCS Research Ethics Committee and granted a favourable ethical opinion. It is envisaged that the findings will be of great relevance to all patients involved and the Island as a whole as well as the wider research community.

What will happen to the results of the study?

The results of the study will be used to develop training materials and resources prior to eventually being disseminated through publications and presentations at conferences. At no time will the identity of the individual participants involved appear in this information. A summary of the research will be printed and distributed to all involved parties.

Thank you for taking the time to read this leaflet.

If wish to have the opportunity to ask any question about the project, please call Dr Alessio Agostinis on 01534 444669 or one of our research team via our team co-ordinator on 01534 445609. Alternatively, email Dr Agostinis on a.agostinis@health.gov.je with your questions or to arrange a suitable time to speak.

Appendix 5: Consent Form

RESEARCH STUDY CONSENT FORM

Research team: Dr Alessio Agostinis (Lead Researcher); Dr Chad Taylor (Sponsor), Dr Nigel Minihane (GP and Jersey Primary Care Body), Dr Ben Rosser (Liverpool John Moores University) Jonathan Bond (Pain Clinic), Colin Duff (Breathworks CIC).

Please tick to confirm

- I have read the information sheet for the above research study ☐
- I have been offered the opportunity to ask questions about the research study via the contact details provided on the research information leaflet . I have either not needed to ask further questions, **or** I have made contact and asked questions at the time of completing this consent form ☐
- I understand the purpose of the research study and how I will be involved ☐
- I understand that all information collected in the research study will be held in confidence and that if it is presented or published, all my personal details will be removed ☐
- I confirm that I will be taking part in this research study of my own free will, and I understand that I may withdraw from it as for the terms stated in the *Participant Information Sheet*, without my normal care being affected ☐
- I understand that if I touch on any matter that raises a concern about the wellbeing or safeguarding of another person or myself, you are duty bound to pass that information on to a relevant agency, which means you are unable to keep such information confidential. ☐
- I understand the requirement for and consent to my GP and/or healthcare records to be checked for the purpose of my suitability to take part in this study. ☐
- I confirm I am 18 years of age or older ☐

I agree to take part in the above research study.

Signed: …….. Date: ……

Print name:…….

Please complete this consent form. If you have any questions about this form or outstanding questions about the study, please call Dr Alessio Agostinis on 01534 444669 or one of our research team via our team co-ordinator on 01534 445609. Alternatively, email Dr Agostinis on a.agostinis@health.gov.je with your questions or to arrange a suitable time to speak

Thank you for taking the time to fill in this consent form, your answers will be very useful to the Research Team.

Appendix 6: Consent Form

RESEARCH STUDY COURSE PROVIDER CONSENT FORM

Research team: Dr Alessio Agostinis (Lead Researcher); Dr Chad Taylor (Sponsor), Dr Nigel Minihane (GP and Jersey Primary Care Body), Dr Ben Rosser (Liverpool John Moores University) Jonathan Bond (Pain Clinic), Colin Duff (Breathworks CIC).

Please tick to confirm

- I have had the opportunity to ask questions about my role as a mindfulness course teacher in the research study directly with a member of the Research team via telephone, email or face to face ☐
- I understand the purpose of the research study and how I will be involved ☐
- I understand that all information collected in the research study will be held in confidence and that if it is presented or published, all my personal details will be removed ☐
- I understand that if I touch on any matter that raises a concern about the wellbeing or safeguarding of another person or me, you are duty bound to pass that information on to a relevant agency, which means you are unable to keep such information confidential. ☐
- I understand that for the purposes of evaluating the fidelity to the Breathworks Mindfulness for Stress or Mindfulness for Health teachers' notes and protocols, I am required and consent to being recorded delivering the mindfulness courses ☐
- I understand that the audio-visual recording of the classes will be evaluated (and scored) by two separate assessors and stored in accordance with relevant data protection and research ethical guidelines. ☐

I agree to take part in the above research study.

Signed: …….. Date: ……

Print name:…….

Please complete this consent form. If you have any questions about this form or outstanding questions about the study, please call Dr Alessio Agostinis on 01534 444669 or one of our research team via our team co-ordinator on 01534 445609. Alternatively, email Dr Agostinis on a.agostinis@health.gov.je with your questions or to arrange a suitable time to speak

Thank you for taking the time to fill in this consent form, your answers will be very useful to the Research Team.

Appendix 7: Risk Assessment Form

Jersey Mindfulness Project – Risk Assessment

Identified Risks	Likelihood	Potential Impact/Outcome	Risk Management/Mitigating Factors
Practicing mindfulness meditation has been known to trigger distressing memories in patients with existing Trauma/PTSD	Low	Participant: • Psychological Stress Researcher • Anxiety about dealing with a complex situation	• Exclusion criteria for enrolling in the study will include those with pre-existing psychiatric comorbidities, particularly Trauma/PTSD conditions • As we are recruiting from primary care GPs will be informed of this criteria as will patients themselves in their information packs • The researcher will be able to signpost participant to the relevant support services
Discussion of sensitive topics in interview has	Low	Participant: • Psychological Stress	• Offer to cease interview • Exclusion criteria (as above)

potential to cause distress to participant		Researcher • Anxiety about dealing with a complex situation	• The researcher will be able to signpost participant to the relevant support services
Conflict between participants in group setting	Low	Participant: • Psychological Stress Researcher • Anxiety about dealing with a complex situation	• The researcher will have the necessary training and experience in group facilitation to handle conflicts
Data collection & interviews may possibly take place in an unfamiliar location with people not already known to the researcher	High	Researcher • Physical Injury or Psychological Harm	• Visit location prior to data collection to assess possible risks associated with built and social environment • Use this information to plan session • Identify back up at location or online preferably • Allow extra time to familiarise participants with research and environment • Researcher to have contact details and means of making timely contact with back up

Disclosure of information about poor practice	Low	Immediate, urgent or prompt response may be required from service providers	• Ensure all verbal and written information about research indicates possible researcher response to disclosure • The researcher will be able to signpost participant to the relevant support services
Disclosure of unmet health or social care needs	Medium	Immediate, urgent or prompt response may be required from service providers	• Ensure all verbal and written information about research indicates possible researcher response to disclosure • The researcher will be able to signpost participant to the relevant support services
Research participant in danger of harm to self or others	Low	Immediate, urgent or prompt response may be required from service providers	• Ensure all verbal and written information about research indicates possible researcher response to disclosure • The researcher will be able to signpost participant to the

			relevant support services

Notes to Applicants

1. The Research Ethics Committee requests that all applicants complete the standard application form in a word processed form. Please note, incomplete forms may result in undue delay in considering your proposal. Applications which are not complete or have missing supplementary documentation will not be passed to the Research Ethics Committee and may be returned.

2. The application form is designed to summarise the information concerning your proposed research in order for the Research Ethics Committee to make an assessment. Please ensure that all sections are completed. (See the checklist page 2 of the application form). All relevant supplementary documentation must be included with your completed application form.

3. Please avoid the use of abbreviations and jargon wherever possible and provide a clear explanation of technical terms used for the benefit of lay committee members.

4. The application form is intended to be largely self-explanatory. However, the following comments may assist in completion of this:

Part 1 – Applicant details

Full details should be given of applicant who is proposing to conduct the research project. This must be signed by an academic or clinical supervisor (depending on who is sponsoring and who is supporting the research).

Part 2 – Introduction

Full details should be given of the research team who will be involved in carrying out the research project. If there is only one researcher/investigator he/she will be the Lead Researcher/Principal Investigator for the purposes of the form.

The sponsoring body must be identified. Researchers should carry personal insurance and/or be covered by insurance, or provision made by the employer.

Research sponsored by a pharmaceutical company requires adherence to Association of the British Pharmaceutical Industry Guidelines.

Research undertaken as part of an academic programme of study must have university sponsorship.

Part 3 – The Research

Section 2 Outline of research

It is important that the committee is made aware of the status and type of participant to be recruited and the criteria for inclusion and exclusion of individuals. Please note that in the case of clinical trials, the relative level of acceptable risk may be greater in therapeutic research in patient volunteers (where there is a balancing factor of potential benefit) than in non-therapeutic research using "healthy volunteers".

You must state whether participants will be selected with specific reference to sex, age group and status. You should make clear what proportion of participants recruited (if any) will act as controls.

The effectiveness and propriety of recruitment and selection procedures must be clear. Participants must not be coerced or induced to participate.

Any conflict of interest must be declared, particularly in cases where a participant's relationship with the researcher could raise issues as to the willingness or motive of the participant in consenting to participation (e.g. students).

Section 3 Ethical issues

In discussing the potential risks and hazards which are associated with the research, applicants are required to specify the degree of probability (e.g. percentage terms or as unlikely, possible, likely, expected) and to categorise the risk (e.g. serious, moderate, minor, negligible or in percentage terms). The committee is concerned about the possibility and

nature of anticipated side effects and the nature and extent of the risks that the participant assumes to physical or mental health and well-being by participation.

Section 4 Informed consent

Informed consent is a requirement from all research participants. Where problems may be encountered as a result of language or hearing difficulties, the applicant must explain how these difficulties are to be handled - e.g. interpreter, translation of documents

In any circumstances where the investigator does not anticipate being in a position to obtain participant consent (e.g. studies involving emergency patients, the unconscious, children under 16 who are not judged competent by the investigator to consent in their own right etc.) the applicant must provide full details of the course proposed to be taken with regard to consent and the justification for it. The answer must address the patient's best interests: i.e. will or could enrolment into the research be of therapeutic value to the individual.

Participant information sheets and consent forms must be prepared and presented as separate documents or as an appendix to the application.

In respect of clinical trial research, the participant's GP should be notified before the research commences. Participant consent to such notification (and to further related communication with the GP if necessary) should therefore generally be incorporated into the consent form (and notice of this requirement added to the information sheet). If you do **not** intend to contact participants' GPs, please give reasons.

Section 8 Vulnerable groups

The need to conduct research in "special" or "vulnerable" groups as listed on the application form should be justified. Clarification that the data required could not be obtained from any other class of participant is required. The needs of special groups may indicate extra safeguards/procedures in relation to the provision of information and consent procedures.

Part 4 – Financial and other arrangements

A full statement should be included of all payments, funding and grants which may be made to, or have been agreed with the applicant, his department or employer in connection with the performance of the research. "Payment" includes donations of equipment or other

appliances. (Such financial support should be related to expenses, costs incurred and resources expended in the conduct of the research).

Documents which must accompany the application for ethical opinion of proposed research, where relevant:

(i) Recruitment advertisement(s) if applicable and any other material proposed to be used for recruitment.

(ii) GP letter, if applicable

(iii) Patient information sheet (and letter of invitation, if applicable).

(iv) Consent form.

(v) Research protocol (research summary).

(vi) Where applicable, a copy of regulatory approval in the form of any product licence, Clinical Trial Certificate (CTC), Clinical Trial Exemption (CTX), Doctor's and Dentist's Exemption (DDX) or other authority in writing i.e. proof of regulatory compliance (not applicable in healthy volunteer studies). **Please note that the authority may not extend to Jersey and, in such circumstances, further approval will need to be sought locally.**

(vii) Data sheet if licensed product(s) are being used in clinical trial research.

(viii) Administration of Radioactive Substances Advisory Committee (ARSAC) approval, where appropriate.

(ix) Where applicable, company confirmation of adherence to relevant Association of the British Pharmaceutical Industry (ABPI) Guidelines.

(x) Risk assessment in compliance with the States of Jersey Health and Social Services, Health and Safety Policy requirements.

(xi) Full MREC application or university REC application if applicable.

(xii) Confirmation of favourable opinion from university faculty REC, if applicable. This may be forwarded after the application.