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The feasibility of student physiotherapists delivering a brief psychological intervention to stroke patients

Submission date	**Recruitment status**	[X] Prospectively registered
21/10/2020	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
16/11/2020	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
16/11/2021	Other	[ ] Record updated in last year

Plain English summary of protocol

Current plain English summary as of 23/03/2021:
Background and study aims
We have undertaken several research studies, which, when combined, have given us a new model to guide specialist practice and training, the Model of Emotions, Adaptation and Hope (MEAH). The MEAH allows us to provide a single e-learning training session which includes: (a) an introduction to the mental health screening of student physiotherapists by self-completing the MEAH questionnaire and considering an introduction to scale (b) teaching of a storytelling-based therapy (underpinned by the MEAH model to enhance interactions) (c) applying the training to a selected group of people with chronic illnesses (individuals identified from the people in research website). We have named this e-learning training package, the Screen, Intervene, and Train (SIT) approach to care. Our past pilot research (Soundy et al., 2020; 2021) has tested the effectiveness of training from a student perspective and research is needed to consider if students can apply the training themselves to participants and consider the feasibility of this.

Our primary aim is to assess the feasibility of students delivering the intervention on people with stroke. We will assess three outcome measures, feasibility related outcomes and consider the therapeutic conversations and record a a single interview with both students and people with stroke post intervention.

Who can participate?
The study will use MEAH trained student physiotherapists who volunteer to provide a screening interview to an individual with stroke.

What does the study involve?
The planned study requires people with Stroke to be allocated to either a control group (waiting list control) or the intervention group (with MEAH training). Patient assessment will take place before and after the intervention. The waiting list control group will receive the MEAH as soon as they would like after completing the post assessment (i.e. 15 minutes after this if required or desired).

What are the possible benefits and risks of participating?
The most direct benefits include; (a) improved mental health for student physiotherapists and participants. (b) empowerment of participants to seek positive coping behaviours, reducing the need for additional costly healthcare services for student physiotherapists and potentially patients. (c) increase resilience of student physiotherapists and reduced burn out (d) improve patient satisfaction and (e) reduced need for pharmacological approaches to treat mental illness student physiotherapists (f) reduced work absence and improved productivity of student physiotherapists and (g) possibility of a new model for clinical placement and experience for students.

The potential risk is that people with stroke are asked to reflect on a current difficulty and rate it. The interview process could bring up memories which cause upset or distress. Our pilot research and patient and participant involvement sessions identified no adverse event however.

When is the study running from?
University of Birmingham (UK)

When is the study starting and how long is it expected to run for?
September 2020 to November 2021

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr A Soundy
A.A.Soundy@bham.ac.uk

Previous plain English summary:
Background and study aims
Currently, student Health Care Professionals (SHCPs) face distinct and unique pressures on their mental health and are experiencing poorer mental health, such as heightened levels of anxiety and depression. Part of this is a result of the interactions that they are required to have with patients and families via remote means (e.g. by phone) due to social distancing and which is highly pressured and intense given the unforeseen impact of the COVID-19 pandemic. The researchers have undertaken many small research studies, which, when combined, have given them a new model to guide specialist practice and training, the Model of Emotions, Adaptation and Hope (MEAH). The MEAH allows the researchers to provide a single e-learning training session which includes: (a) mental health screening of SHCP by self-completing the MEAH questionnaire, (b) a brief mental health intervention involving a 20-minute e-based or telephone call around the screening and (c) teaching of a storytelling-based therapy (underpinned by the MEAH model to enhance interactions). They have named this e-learning training package the Screen, Intervene, and Train (SIT) approach to care. The aim of this study is to investigate the impact of a 2-hour MEAH e-learning training session on depression and anxiety of SHCPs.

Who can participate?
Students who are completing a UK health care course at a participating university

What does the study involve?
Students participate in one of three groups for a period of 2 hours. All active groups or interventions are delivered virtually. The SIT intervention will include a single screening interview taking 20 minutes with Dr A Soundy. Following this, the participant will be sent a pre-recorded e-based training session. The lecture takes 45 minutes. The indicative content

considers examples of interactions, the science behind the MEAH, the use of screening and how to engage in a brief narrative-based intervention within practice. It has the same components as the pilot studies, although adapted into one training session. The final part of the training for SHCP will include an e-learning presentation. The presentation will provide an analysis of the screening calls. This will reveal the most common difficulties and stories expressed within screening and will summarise the difficulties that were challenging to adapt to, an illustration of how the MEAH is important for this understanding and the most common coping strategies identified (this was undertaken and achieved as part of the pilot research to consolidate learning). The principles are that sharing this information will provide direct access to others' experiences which has been associated with enhanced mental health outcomes. The benefit of this is SHCP can access effective coping strategies that promote mental health and psychological well-being outcomes. This entire process will take a maximum of 2 hours to complete at a pace and time that is convenient for the participant. The inactive waiting list control group will receive or be offered the SIT intervention at week 12. Individuals in this group will receive or be offered the SIT intervention at week 12. The follow-up assessment for all groups will be at 3 months.

What are the possible benefits and risks of participating?
There may be mental health benefits for the student with improved communication skills and better psychological care for the patient.

Where is the study run from?
University of Birmingham (UK)

When is the study starting and how long is it expected to run for?
September 2020 to September 2021

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr A Soundy
A.A.Soundy@bham.ac.uk

Study website
https://www.meah.rocks

Contact information

Type(s)
Scientific

Contact name
Dr Andrew Soundy

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
The feasibility of Student Physiotherapists of delivering a brief psychological intervention; a feasibility study

Acronym
PT-MEAH

Study objectives
Current study hypothesis as of 23/03/2021:
Student health care professionals who are trained to use the model of emotions, adaptation and hope are able to effectively support participants with stroke.

Previous study hypothesis as of 08/01/2021:
Student health care professionals who are training using the model of emotions, adaptation and hope will obtain mental health and interactional benefits compared to a waiting list control condition.

Previous study hypothesis:
Student health care professionals who are training using the model of emotions, adaptation and hope will obtain mental health and interactional benefits compared to motivational interviewing and a waiting list control condition.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Current ethics approval as of 23/03/2021:
Approval pending, Science, Technology, Engineering and Mathematics Ethical Review

Committee (Research Support Group, C Block Dome, Aston Webb Building, University of Birmingham, Edgbaston, B15 2TT, UK; +44 (0)121 414 8825; s.l.cottam@bham.ac.uk), ref: ERN_18-1970E

Previous ethics approval:
Approved 29/09/2019, Science, Technology, Engineering and Mathematics Ethical Review Committee (Research Support Group, C Block Dome, Aston Webb Building, University of Birmingham, Edgbaston, B15 2TT, UK; +44 (0)121 414 8825; s.l.cottam@bham.ac.uk), ref: ERN_18-1970D

Study design
Single centre multi method study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Internet/virtual

Study type(s)
Other

Participant information sheet
https://www.meah.rocks/information-sheet-national-student-

Health condition(s) or problem(s) studied
Training of student health care professionals to deliver support to people with stroke

Interventions
Current interventions as of 23/03/2021:
Stroke participants will be required to complete baseline outcome measure and then will be randomised to either an intervention condition or waiting list control (15-minute wait). For the intervention group, trained physiotherapy students will provide a brief (5 - 15 minute) one-to-one video intervention.
After the intervention the measures will be repeated.

The training provided to the students will include a single screening interview taking 20 minutes with Dr A Soundy. Following this, the participant will be sent a pre-recorded e-based training session. The lecture takes 45 minutes. The indicative content considers examples of interactions, the science behind the MEAH, the use of screening and how to engage in a brief narrative-based intervention within practice. It has the same components as the pilot studies, although adapted into one training session. The final part of the training for SHCP will include an e-learning presentation. The presentation will provide an analysis of the screening calls. This will reveal the most common difficulties and stories expressed within screening and will summarise the difficulties that were challenging to adapt to, an illustration of how the MEAH is important for this understanding and the most common coping strategies identified (this was undertaken and achieved as part of the pilot research to consolidate learning). The principles are that sharing this information will provide direct access to others' experiences which has been associated with

enhanced mental health outcomes (Ooms et al., 2016; Soundy et al., 2019). The benefit of this is SHCP can access effective coping strategies that promote mental health and psychological well-being outcomes. This entire process will take a maximum of two hours to complete at a pace and time that is convenient for the participant.

Previous interventions as of 08/01/2021:
Group 1. Model of emotions, adaptation and hope
Group 2. Waiting list control

Group 1 intervention: the SIT intervention will include a single screening interview taking 20 minutes with Dr A Soundy. Following this, the participant will be sent a pre-recorded e-based training session. The lecture takes 45 minutes. The indicative content considers examples of interactions, the science behind the MEAH, the use of screening and how to engage in a brief narrative-based intervention within practice. It has the same components as the pilot studies, although adapted into one training session. The final part of the training for SHCP will include an e-learning presentation. The presentation will provide an analysis of the screening calls. This will reveal the most common difficulties and stories expressed within screening and will summarise the difficulties that were challenging to adapt to, an illustration of how the MEAH is important for this understanding and the most common coping strategies identified (this was undertaken and achieved as part of the pilot research to consolidate learning). The principles are that sharing this information will provide direct access to others' experiences which has been associated with enhanced mental health outcomes (Ooms et al., 2016; Soundy et al., 2019). The benefit of this is SHCP can access effective coping strategies that promote mental health and psychological well-being outcomes. This entire process will take a maximum of two hours to complete at a pace and time that is convenient for the participant.

Group 2 inactive control: an inactive waiting list control group will be used. Individuals in this group will receive or be offered the SIT intervention at week 12.

Previous interventions:
Group 1. Model of emotions, adaptation and hope
Group 2. Motivational interviewing
Group 3. Waiting list control

Intervention: The SIT intervention will include a single screening interview taking 20 minutes with Dr A Soundy. Following this, the participant will be sent a pre-recorded e-based training session. The lecture takes 45 minutes. The indicative content considers examples of interactions, the science behind the MEAH, the use of screening and how to engage in a brief narrative-based intervention within practice. It has the same components as the pilot studies, although adapted into one training session. The final part of the training for SHCP will include an e-learning presentation. The presentation will provide an analysis of the screening calls. This will reveal the most common difficulties and stories expressed within screening and will summarise the difficulties that were challenging to adapt to, an illustration of how the MEAH is important for this understanding and the most common coping strategies identified (this was undertaken and achieved as part of the pilot research to consolidate learning). The principles are that sharing this information will provide direct access to others' experiences which has been associated with enhanced mental health outcomes (Ooms et al., 2016; Soundy et al., 2019). The benefit of this is SHCP can access effective coping strategies that promote mental health and psychological well-being outcomes. This entire process will take a maximum of two hours to complete at a pace and time that is convenient for the participant.

Inactive control group 1: an inactive waiting list control group will be used. Individuals in this group will receive or be offered the SIT intervention at week 12.

Active control group 2: an alternative e-intervention will be used which includes a 45-minute pre-recorded lecture. Individuals in this group will receive or be offered the SIT intervention at week 12.

Intervention Type
Behavioural

Primary outcome measure
Current primary outcome measure as of 23/03/2021:
Patient-reported outcome measures will be taken before and after the intervention:
1. Fatigue measured using the fatigue severity scale
2. Impact of health on an individual's everyday life measured using the SF-12
3. Emotions, adaptation and hope measured using the MEAH version 3.3 (made up of the hope and adaptation scale (Soundy et al., 2016) and the circumplex model of affect (Russell, 1980))

Previous primary outcome measure:
Depression and anxiety measured using The Hospital Anxiety and Depression Scale (HADS) pre, immediately post intervention, and at 12 weeks

Secondary outcome measures
Current secondary outcome measures as of 23/03/2021:
1. Personal perceptions and experiences of the process and how it could fit into everyday practice for physiotherapist measured using student physiotherapist and patient interviews will be undertaken after the intervention
2. Interactions will be recorded to analyse if the student can apply the principles of the training and manage interactions using the MEAH

Previous secondary outcome measures:
Measured pre, immediately post intervention, and at 12 weeks:
1. Quality of life measured using the SF-12 quality of life questionnaire
2. Stigmatising attitudes and intentions of behaviour measured using the open minds scale for health care providers
3. Communication assessed using the Froehlich Communication Survey
4. Empathy measured using the interpersonal reactivity index
5. Hope measured using the Adult Hope Scale
6. Emotions, adaptation and hope measured using the MEAH version 3.3

Overall study start date
01/09/2020

Completion date
01/11/2021

Eligibility

Key inclusion criteria
Current inclusion criteria as of 23/03/2021:
1. Students

1.1. Have received MEAH training
1.2. Currently completing a BSc Physiotherapy degree

2. People with stroke
2.1. Not currently an NHS patient
2.2. No cognitive impairments
2.3. Community dwelling

Previous participant inclusion criteria as of 08/01/2021:
Any student health care professional currently studying at one of the following Universities:
1. University of Birmingham
2. Winchester University
3. Oxford Brookes University

Previous participant inclusion criteria:
Any student health care professional currently studying at one of the following Universities:
1. Southampton University
2. Birmingham City University
3. Oxford Brookes University
4. Coventry University
5. Nottingham University

Participant type(s)
Mixed

Age group
Adult

Sex
Both

Target number of participants
30

Key exclusion criteria
Current exclusion criteria as of 23/03/2021:
1. Student
Participated in the pilot study or received training related to the model previously in any form

2. People with stroke
Does not meet inclusion criteria

Previous participant exclusion criteria as of 08/01/2021:
1. Participated in the pilot study or received training related to the model previously in any form

Previous participant exclusion criteria:
1. Participated in the pilot study

Date of first enrolment
01/05/2021

Date of final enrolment
01/11/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Birmingham
School of Sport, Exercise and Rehabilitation Sciences
Brimingham
United Kingdom
B15 2TT

Study participating centre
Faculty of Health and Well Being
Department of Health and Care Professions
University of Winchester
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SO23 9AH

Study participating centre
Oxford Brookes University
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Study participating centre
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Sponsor information

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Sponsor type
University/education

Website
http://www.birmingham.ac.uk/index.aspx

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/12/2021

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version v2.6	08/09/2020	02/12/2020	No	No