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Cognitive behavioural therapy in primary health care for persistent physical symptoms

Submission date
21/06/2021

Recruitment status
No longer recruiting

Registration date
03/08/2021

Overall study status
Completed

Last Edited
27/08/2025

Condition category
Signs and Symptoms

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Persistent physical symptoms (PSS) are distressing and/or disabling symptoms that cannot be explained by biological or physical factors. This means that despite thorough investigation the symptoms cannot be accounted for by any known disease, physical aspects of mental disorders or the effects of substances. Many different types of PPS have been described and some defined as separate syndromes. Such syndromes are found in most medical specialities, such as irritable bowel syndrome, chronic fatigue, fibromyalgia, non-cardiac chest pain, premenstrual syndrome and chronic pain. Although these syndromes belong to different medical specialities there is considerable overlap between individual syndromes and similarities in their definitions. Additionally, people often suffer from more than one unexplained symptom or syndrome at the same time.
PPS are very common in all healthcare settings and studies show that patients with PPS use more healthcare resources than patients suffering from medically explained conditions. However, the healthcare consultations do not lead to demonstrable symptom improvement or reduction in distress caused by the symptoms. Recently it has been shown that specific types of PPS syndromes can be treated effectively with cognitive behaviour therapy (CBT). However, people with more than one PPS would need to undergo more than one treatment to manage their symptoms, and there are in some instances more than one version of CBT for particular PPS, creating practical issues in terms of training of clinicians and delivery of treatment. To address this issue, the researchers and their collaborators have developed a new group CBT treatment that both addresses factors common amongst all PPS and factors specific to each type of PPS. The main goal of this study is to implement this new treatment and to evaluate whether it is more effective in reducing PPS and mental distress related to them than the treatment usually provided to these patients.

Who can participate?
Adult men and women aged over 18 years who seek primary care services and are experiencing PPS.

What does the study involve?
Participants will be randomly assigned into two groups: the usual care group and the CBT group. The usual care group will receive the current standard treatment for PPS which most often

involves individual treatment with a psychologist or a physiotherapist. The CBT group will receive the 12-week group therapy for PPS, once to twice a week for 2 hours. The therapy is a hybrid of general and specific components, consisting of a general component involving helping participants to understand how their physical and psychological reactions impact each other (regardless of the type of PPS) followed by a specific component where participants with similar PPS come together to focus on the symptoms they experience. Five times during the study participants in both the usual care group and the CBT group will answer questionnaires about their symptoms, mental health and impairment in daily life. Their answers will be used to determine whether the new therapy works better at reducing PPS, mental distress and impairment than the usual care.

What are the possible benefits and risks of participating?
There are minimal risks to participating in the study. The benefits are considerable as participants will potentially receive effective treatment for their PPS based on the current scientific understanding in the field. Although people may experience mild discomfort during treatment, for example having to face difficult emotions and thoughts and trying to use different coping strategies to their normal ones. The risk associated is minimal and is likely to be outweighed by the positive impact of cognitive behavioural therapy.

Where is the study run from?
1. University of Reykjavík (Iceland)
2. University of Oxford (UK)
3. University of Iceland (Iceland)

When is the study starting and how long is it expected to run for?
February 2016 to April 2025

Who is funding the study?
RANNÍS (Icelandic Centre for Research) (Iceland)

Who is the main contact?
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Additional identifiers

Protocol serial number
VSN-16-045

Study information

Scientific Title
Evaluation of the clinical effectiveness and economic impact of a hybrid transdiagnostic cognitive behavioural treatment for persistent physical symptoms among adults seeking primary health care in Iceland: a randomized clinical trial

Acronym
CBT-PriPPS

Study objectives
1. Hybrid transdiagnostic cognitive behavioural therapy will be more clinically effective in addressing functional impairment accompanied by persistent physical symptoms than usual care.
2. Hybrid transdiagnostic cognitive behavioural therapy will be more clinically effective in addressing persistent physical symptoms than usual care.
3. Hybrid transdiagnostic cognitive behavioural therapy of persistent physical symptoms (PPS) will not be significantly more expensive than usual care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/04/2016, Vísindasiðanefnd (National Bioethics Committee of Iceland, Borgartún 21, 105 Reykjavík, Iceland; +354 (0)551 7100; vsn@vsn.is), ref: VSN-16-045

Study design
Single-centre interventional randomized clinical trial, stratified randomisation without replacement

Primary study design
Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied
Persistent physical symptoms accompanied by anxiety and/or depressive symptoms

Interventions
Current intervention as of 11/10/2022:
During recruitment, health care workers of participating primary health care clinic will refer patients to the study if there is a suspicion of persistent physical symptoms (PPS). All individuals that speak Icelandic, have PPS and accept psychological treatment of their symptoms will be offered participation in the study. Interested participants will be thoroughly assessed in an intake interview by trained psychologists using both a structured interview and a standardized psychiatric interview (MINI). The intake interview will provide important information about the mental state and basic cognitive ability of participants to evaluate eligibility.

Eligible participants will complete a baseline assessment battery and be randomized into the Usual Care Intervention Group and Experimental Intervention Group (60 individuals in each group) using stratified randomisation without replacement.

Participants in the Usual Care Intervention Group will follow the usual procedure by the primary health care clinic.

Participants in the Experimental Intervention Group receive a 8-week hybrid transdiagnostic cognitive behavioural therapy for their PPS in a group setting, twice a week for 2 hours. The intervention consists of two components. Firstly, non-specific CBT for all PPS which includes formulation, psychoeducation, becoming familiar with the basic cognitive behavioural model for PPS, addressing common factors of different PPS and preparation for working with more specific symptoms. Secondly, specific CBT with focus on factors specific to different types of PPS. The treatment manual contains six modules relating to six common types of PPS that can be used according to participants' needs. The six modules pertain to:
1. Sleep problems
2. Pain
3. Chronic tiredness, fatigue and/or muscle problems
4. Gastrointestinal problems
5. Heart and chest symptoms
6. Dizziness and/or related problems

Previous intervention:
During recruitment, new clients of the VIRK – Vocational Rehabilitation Fund will be systematically screened for persistent physical symptoms (PPS). All individuals that speak Icelandic, have PPS and accept psychological treatment of their symptoms will be offered participation in the study. Interested participants will be thoroughly assessed in an intake interview by trained psychologists using both a structured interview and a standardized psychiatric interview (MINI). The intake interview will provide important information about the mental state and basic cognitive ability of participants to evaluate eligibility.

Eligible participants will complete a baseline assessment battery and be randomized into the Usual Care Intervention Group and Experimental Intervention Group (125 individuals in each group) using stratified randomisation without replacement.

Participants in the Usual Care Intervention Group will follow the usual procedure by VIRK which typically involves individual treatment with a psychologist or a physiotherapist on a contract with VIRK.

Participants in the Experimental Intervention Group receive a 12-week hybrid transdiagnostic cognitive behavioural therapy for their PPS in a group setting, once to twice a week for 2 hours. The intervention consists of two components. Firstly, 6 weeks of non-specific CBT for all PPS which includes formulation, psychoeducation, becoming familiar with the basic cognitive behavioural model for PPS, addressing common factors of different PPS and preparation for working with more specific symptoms. Secondly, 6 further weeks of group treatment that focus on factors specific to different types of PPS. The treatment manual contains seven modules relating to seven common types of PPS that can be used according to participants' needs. The seven modules pertain to (1) sleep problems, (2) pain, (3) chronic tiredness, fatigue and/or muscle problems, (4) gastrointestinal problems, (5) heart and chest symptoms, (6) dizziness and /or related problems, and (7) gynaecological problems.

Intervention Type
Behavioural

Primary outcome(s)
Current primary outcome measure as of 11/10/2022:
Impairment in mental health functioning in terms of work, home management, leisure and close relationships, measured with the Work and Social Adjustment Scale (WSAS) at baseline, after 4 weeks of treatment, after 8 weeks of treatment, and 3-month and 6-month follow-up

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Previous primary outcome measure:
Impairment in mental health functioning in terms of work, home management, leisure and close relationships, measured with the Work and Social Adjustment Scale (WSAS) at baseline, after 6 weeks of treatment, after 12 weeks of treatment, and 3-month and 6-month follow up

Key secondary outcome(s))
Current secondary outcome measures as of 11/10/2022:
1. Presence and severity of PPS, measured using The Persistent Physical Symptom Checklist (PPSC) at baseline, after 4 weeks of treatment, after 8 weeks of treatment, and 3-month and 6-month follow-up
2. Questionnaire measure of their identified main psychological problem:
2.1. Depression measured using Patient Health Questionnaire-9 (PHQ-9) at baseline, after 4 weeks of treatment, after 8 weeks of treatment, and 3-month and 6-month follow-up
2.2. General anxiety measured using General Anxiety Disorder-7 (GAD-7) at baseline, after 4 weeks of treatment, after 8 weeks of treatment, and 3-month and 6-month follow-up
2.3. Health anxiety measured using Short Health Anxiety Inventory (SHAI) at baseline, after 4 weeks of treatment, after 8 weeks of treatment, and 3-month and 6-month follow-up

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Previous secondary outcome measures:
1. Presence and severity of PPS, measured using The Persistent Physical Symptom Checklist (PPSC) at baseline, after 6 weeks of treatment, after 12 weeks of treatment, and 3-month and 6-month follow up
2. Questionnaire measure of their identified main psychological problem:

2.1. Depression measured using Patient Health Questionnaire-9 (PHQ-9) at baseline, after 6 weeks of treatment, after 12 weeks of treatment, and 3-month and 6-month follow up
2.2. General anxiety measured using General Anxiety Disorder-7 (GAD-7) at baseline, after 6 weeks of treatment, after 12 weeks of treatment, and 3-month and 6-month follow up
2.3. Health anxiety measured using Short Health Anxiety Inventory (SHAI) at baseline, after 6 weeks of treatment, after 12 weeks of treatment, and 3-month and 6-month follow up

Completion date
30/04/2025

Eligibility

Key inclusion criteria
Current inclusion criteria as of 11/10/2022:
1. Referred to the study by primary care professionals between January 2022 and October 2022
2. Experience persistent physical symptoms that influence impairment in everyday life
3. Scoring above threshold on one of the following psychological measures: PHQ-9, GAD-7 or SHAI
4. Aged over 18 years of age
5. At assessment, say they will accept psychological treatment of their symptoms

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Previous inclusion criteria:
1. Referred to VIRK for work rehabilitation between September 2021 and December 2022
2. Experience persistent physical symptoms which influence their workability
3. Scoring above threshold on one of the following psychological measures, PHQ-9, GAD-7 or SHAI
4. Over 18 years of age
5. At assessment, say they will accept psychological treatment of their symptoms

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
65

Key exclusion criteria

1. Do not speak/read Icelandic
2. Serious physical or mental health problems that affect participation in treatment, e.g. current psychotic symptoms, active substance abuse

Date of first enrolment
01/04/2023

Date of final enrolment
15/11/2024

Locations

Countries of recruitment
Iceland

Study participating centre
Unknown
Unknown
Iceland
101

Sponsor information

Organisation
Reykjavík University

ROR
https://ror.org/05d2kyx68

Funder(s)

Funder type
Government

Funder Name
Icelandic Centre for Research

Alternative Name(s)
Rannsóknamiðstöð Íslands, RANNIS

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Iceland

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available as our ethical permit does not allow it. The data can be made available on request from Sigrún Ólafsdóttir Flóvenz, sigrunola@ru.is.

IPD sharing plan summary
Not expected to be made available