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Effectiveness of psychotherapy in patients with medically unexplained physical symptoms

Submission date
09/05/2018

Recruitment status
No longer recruiting

Registration date
14/05/2018

Overall study status
Completed

Last Edited
05/07/2022

Condition category
Signs and Symptoms

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Background and study aims
Mental health professionals, as well as doctors, often see patients presenting physical symptoms for which a physical cause is either absent or does not explain these complaints sufficiently. While in general language these conditions are often called “psychosomatic” (caused by a mental factor) the term “medically unexplained physical symptoms” (MUPS) has been coined in the medical context. Given the importance of psychological factors in the cause of MUPS, psychological treatments represent a promising approach to the treatment of patients with MUPS. However, reviews and meta-analyses have shown that while various forms of psychological treatments are effective in the treatment of MUPS, the ability to get results is rather low. While some studies indicated that higher effects may be achieved by longer treatments and by more complex approaches, the volume of research is small. Therefore, the full potential of psychological treatments for MUPS remains unexplored.
This study aims to assess the effectiveness of a multi-component psychological treatment in the treatment of patients with MUPS and to examine the process of the therapeutic change.

Who can participate?
Adult patients aged over 18 years who enter group-based psychological treatment in the participating clinics.

What does the study involve?
Participants receive a psychological treatment made up of group psychotherapy, supplemented by activities such as relaxation training, yoga, and art therapy. It is provided on daily basis (5 days /week) for a period of 6 to 12 weeks.

What are the possible benefits and risks of participating?
We do not anticipate any side effects of the participation in our study.

Where is the study run from?
1. Psychosomatic Clinic, Prague (Czech Republic)
2. Psychotherapeutic and Psychosomatic Clinic ESET, Prague (Czech Republic)
3. Day Care Center „Karlov”, Psychiatric Clinic of the General University Hospital in Prague (Czech Republic)

4. Day Care Center Horní Palata, General University Hospital in Prague (Czech Republic)
5. Psychiatric Hospital, Šternberk (Czech Republic)

When is the study starting and how long is it expected to run for?
January 2018 to December 2020

Who is funding the study?
The Czech Science Foundation (Czech Republic)
Grantová Agentura České Republiky

Who is the main contact?
Dr Tomáš Řiháček (Scientific)
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
GA18-08512S

Study information

Scientific Title

Effectiveness of psychotherapy in patients with medically unexplained physical symptoms: A multi-site naturalistic study

Study objectives
EFFECTIVENESS HYPOTHESES
H1: Patients with medically unexplained physical symptoms (MUPS) report decrease in the intensity of MUPS after psychotherapy (primary outcome).
H2: Patients with MUPS report decrease in depression after psychotherapy.
H3: Patients with MUPS report decrease in anxiety after psychotherapy.
H4: Patients with MUPS report decrease in general distress after psychotherapy.
H5: Patients with MUPS report increase in well-being after psychotherapy.
H6: Patients with MUPS report increase in role functioning after psychotherapy.

CHANGE MECHANISM HYPOTHESES
H7: Decrease in MUPS intensity is preceded by increase in somatic awareness.
H8: Decrease in MUPS intensity is preceded by increase in emotional regulation skills.
H9: Decrease in MUPS intensity is preceded by increase in acceptance of symptoms.
H10: Decrease in MUPS intensity is preceded by increase in satisfaction of a patient's relational needs.
H11: Decrease in MUPS intensity is preceded by increase in the clarification of meaning.
H12: Decrease in MUPS intensity is predicted by the quality of therapeutic alliance.
H13: Decrease in MUPS intensity is predicted by the quality of group cohesion.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Research Ethics Committee of Masaryk University, 30/01/2018, ref: EKV-2017-029-R1
2. Ethics Committee of the General University Hospital Prague, 15/02/2018, ref: 2143/17 S-IV

Study design
Multicentre pre-post study of psychotherapy effectiveness

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Medically unexplained physical symptoms (MUPS)

Interventions
Multi-component psychological treatment is provided to all participants on a daily basis. The core of the treatment is group psychotherapy provided with a frequency of 2 to 5 times a week for a period of 6 to 12 weeks, supplemented by activities such as relaxation training, yoga, and art therapy. This is a naturalistic study and the intervention is not at the discretion of the investigator. While the composition of the treatment package differs slightly across participating clinics, the defining aspect (i.e., group psychotherapy) is present in all settings.

Intervention Type
Behavioural

Primary outcome measure
Intensity of medically unexplained physical symptoms is measured using PHQ-15 at the beginning of the treatment, weekly during the treatment, at termination, and 6 and 12 months after termination.

Secondary outcome measures
SECONDARY OUTCOMES
1. General distress is measured using ORS at the beginning of treatment, weekly during treatment, and at termination.
2. Depression is measured using PHQ-9 at the beginning of treatment, at termination, and 6 and 12 months after termination.
3. Anxiety is measured using GAD-7 at the beginning of treatment, at termination, and 6 and 12 months after termination.
4. Well-being is measured using WHO-5 at the beginning of treatment, at termination, and 6 and 12 months after termination.
5. Role functioning is measured using selected items from PHQ at the beginning of treatment, at termination, and 6 and 12 months after termination.

HYPOTHESIZED MEDIATORS OF CHANGE WHICH, THEMSELVES, REPRESENT SECONDARY OUTCOMES
6. Somatic awareness is measured using MAIA at the beginning of treatment, weekly during treatment, and at termination.
7. Emotion regulation skills are measured using ERSQ at the beginning of treatment, weekly during treatment, and at termination.
8. Acceptance of symptoms is measured using CPAQ modified at the beginning of treatment, weekly during treatment, and at termination.
9. Satisfaction of relational needs is measured using RNS-20 at the beginning of treatment, weekly during treatment, and at termination.

Overall study start date
01/01/2018

Completion date
31/12/2020

Eligibility

Key inclusion criteria

1. Age of 18 or more years
2. Occurrence of at least one somatic symptom with a duration of at least six months not fully explained by any somatic diagnosis

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
500

Total final enrolment
444

Key exclusion criteria
1. Diagnosis of a severe mental disorder that would make participation in this kind of treatment impossible
2. Diagnosis of an organic disease responsible for the symptoms

Note: All patients willing to participate are included in the study. Primary analysis is conducted on patients with MUPS. Secondary analyses, however, are conducted on the whole sample (i.e., including patients without somatic symptoms and those with somatic symptoms explained by an organic disease).

Date of first enrolment
26/01/2018

Date of final enrolment
31/12/2019

Locations

Countries of recruitment
Czech Republic

Study participating centre
Psychosomatická klinika
Patočkova 3

Prague
Czech Republic
169 00

Study participating centre
Denní sanatorium Horní Palata Všeobecné fakultní nemocnice v Praze a 1. lékařské fakulty Univerzity Karlovy
U Nesypky 28
Prague
Czech Republic
150 00

Study participating centre
Denní stacionář Karlov Všeobecné fakultní nemocnice v Praze a 1. lékařské fakulty Univerzity Karlovy
Ke Karlovu 11
Prague
Czech Republic
121 08

Study participating centre
Psychoterapeutická a psychosomatická klinika ESET
Úvalská 47
Prague
Czech Republic
100 00

Study participating centre
Psychiatrická nemocnice Havlíčkův Brod
Rozkošská 2322
Havlíčkův
Brod
Czech Republic
580 01

Study participating centre
Psychiatrická klinika Fakultní nemocnice Hradec Králové
Sokolská 581
Hradec

Králové
Czech Republic
500 05

Study participating centre
Fakultní nemocnice Ostrava, Oddělení psychiatrické
17. listopadu 5
Ostrava-Poruba
Czech Republic
708 52

Sponsor information

Organisation
Faculty of Social Studies, Masaryk University

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Brno
Czech Republic
602 00

Sponsor type
University/education

Website
http://fss.muni.cz

ROR
https://ror.org/02j46qs45

Funder(s)

Funder type
Research organisation

Funder Name
Grantová Agentura České Republiky

Alternative Name(s)
Grant Agency of the Czech Republic, Czech Science Foundation, Grantová agentura ČR, Grantové agentury, GrantovaAgentura, GAČR, GACR, GA ČR, GA CR

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Czech Republic

Results and Publications

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

Intention to publish date
31/12/2022

Individual participant data (IPD) sharing plan
Current IPD sharing statement as of 26/03/2019:
The individual participant questionnaire data collected during the trial will be shared, after deidentification. The data will be made available upon reasonable request for three years after the end of the project. Afterwards, it will be made available to anyone who wishes to access it with no end date. The Data Set, Statistical Analysis Plan and Analytic Code will be made available at https://osf.io/dfrma/

Previous IPD sharing statement:
The datasets generated during and/or analysed during the current study are/will be available upon request from Tomáš Řiháček, rihacek@fss.muni.cz

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/07/2022	04/07/2022	Yes	No