

Breitbart's* Meaning Centered Psychotherapy for MND patients: a pilot study of an online psychological intervention.

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Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON52887

Source

ToetsingOnline

Brief title

i-BMCP study

Condition

- Other condition
- Neuromuscular disorders
- Adjustment disorders (incl subtypes)

Synonym

distress, meaning of life, Motor Neuron Disease

Health condition

distress bij ALS of PSMA

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: distress, meaning, Motor Neuron Disease (MND), psychological intervention

Outcome measures

Primary outcome

To explore the efficacy of the intervention in MND patients a single case experimental design will be used with multiple measurements (pre- during -and post measurements) on the primary outcome: Distress with the Hospital Anxiety and Depression scale (HADS).

Secondary outcome

Secondary outcomes will be measured pre and post intervention and will include: Quality of life with the Mc Gill Quality of Life questionnaire part A and B, Personal Meaning measured by The Dutch Personal Meaning Profile (PMP), Post traumatic Growth measured by the Dutch Post Traumatic Personal Growth Inventory (PTGI), and well-being measured by the short form of the Ryffs* scale of psychological Well-being (SPWB).

Study description

Background summary

Patients diagnosed with Amyotrophic Lateral Sclerosis (ALS) or Progressive Muscular Atrophy (PMA), collectively referred to as Motor Neuron Disease (MND),

are at increased risk for emotional distress. Psychological treatment can help patients cope with the strains of living with ALS or PMA, and the relentless progressive decline of physical functioning and early death. However, there is currently insufficient evidence to recommend a specific psychotherapeutic intervention.

In our previous qualitative study on hope in dyads with MND, living a meaningful life was found to play an important role in keeping emotional equilibrium, in line with findings in other terminal illnesses. Breitbart's Meaning Centred Psychotherapy (BMCP) has been found to be well-accepted and effective in advanced cancer patients. BMCP is a time-limited, manualized psychotherapy, focussing on sense of meaning and thereby relieving distress and promoting psychological well-being. To date, BMCP has not been studied in MND patients.

Study objective

It is our aim to adjust BMCP for MND patients with elevated levels of emotional distress. The intervention will be offered via Internet combined (blended) with face to face sessions. Further referred to as internet based BMCP (i-BMCP). Compared to conventional face to face delivery, using the internet will allow wider availability, more flexibility and reduce the number of clinic visits and thereby lowering the burden on the participating MND patients. This study aims to answer the following questions with regard to i-BMCP in MND:

4. 1. Is it acceptable, feasible and are patients satisfied?
5. 2. Does it result in reduced distress and does it enhance the sense of meaning in life?

Study design

We will use a mixed method design, collecting quantitative and qualitative data. We will apply a replicated AB single-case experimental (SCE) design with intervention startpoint randomization and individual semi structured interviews in a five patients .

Intervention

Meaning Centered Psychotherapy (MCP) was originally developed by Breitbart and colleagues as a group intervention and subsequently adapted to an individualized format. The intervention focusses on helping patients with advanced cancer develop or increase a sense of meaning in their lives. Both group and individual BMCP have shown efficacy in 6 RCTs as a treatment for psychological and existential distress in patients with advanced cancer. In randomized controlled trials significant treatment effects were observed in comparison with usual care and/or supportive psychotherapy.

This manualized intervention is grounded in the work of Victor Frankl and utilizes didactics and experiential exercises that focus around themes related to meaning in life and cancer. Each session addresses specific themes related to an exploration of the concepts and sources of meaning, the relationships and impact of disease on one's sense of meaning and identity, and placing one's life in a historical and personal context (i.e. understanding one's legacy). Patients are asked to reflect on their life and on their the most significant memories, relationships, traditions etc. that have made the greatest impact on who they are today.

In addition to the intake there will be 7 weekly sessions. The third session is a video contact session and the last session is face to face or a video session (patients' choice). Session 2, 4, 5, and 6 are online with therapeutic feedback on the mostly narrative assignments. The narrative assignments in this online version are self-administrated, which allow for flexibility of timing and only the intake is a physical face to face contact which lessens the burden of traveling to the clinic for the patients. The evaluation session 7 can be a face to face or a video contact depending on the patient choice.

After the last session and measurement the interview (by video contact or telephone) will be conducted by an independent interviewer.

This psychotherapeutic approach seems well-suited to address the existential issues encountered by MND patients and strongly overlap with the problems experienced by patients diagnosed with advanced cancer. Anecdotal evidence indeed suggests that using elements of BMCP in face-to-face consultations is well-received by MND patients, but further research is warranted. Moreover, patients with MND often face difficulties with progressive immobility and speech problems and offering a predominantly online therapy is patient friendly, lowering physical barriers and making psychological support easy accessible.

Study burden and risks

Participation is voluntary with a low study burden. Participants are already receiving medical care at the Amsterdam UMC and offered a supplementary online intervention blended with a limited number of visits to the clinic. The intervention (8 sessions x 45 min) is likely to be of benefit, with a very low anticipated risk of participating in the intervention for the selected group of patients. No medical invasive diagnostics are employed, only a short interview (max 30 min) and self-report measures that can be filled out online. Some measurements are frequently administered during the control condition (max 10 weeks), during intervention (8 weeks) and during 10 weeks after the intervention, yet these are very short (3-5 minutes). Pre and post assessments (20 min) are scheduled only twice.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

- a) Having a diagnosis of ALS or PMA according to EL Escorial criteria
- b) Reporting to feel distressed (a score of 8 or higher on either the Anxiety or the Depression subscale on the Hospital Anxiety and Depression scale (HADS)).
- c) Being of the age of 18 years or older.
- d) Being able to communicate in Dutch.
- e) Having access to internet at home and being able to work with a computer (or laptop, tablet)
- f) Availability for the duration of the study

Exclusion criteria

Patients cannot participate in the study in case of :

- a) An associated diagnosis of Fronto Temporal Dementia (FTD)
- b) Diagnosis of a current severe psychiatric disorder ,eg Psychosis or Schizophrenia for which psychiatric treatment is undergoing or indicated .
- c) Short life expectancy less than 8 months (as estimated by the physician based on the ALS prediction model)
- d) Not being physically capable of using a device (computer, tablet).

Study design

Design

Study type:	Interventional
Intervention model:	Other
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL	
Recruitment status:	Completed
Start date (anticipated):	17-02-2022
Enrollment:	5
Type:	Actual

Ethics review

Approved WMO	
Date:	30-03-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL71883.018.19