A Mindfulness-Based Stress Reduction programme in at-risk mutation carriers of genetic frontotemporal dementia

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The present study aims to investigate whether a standardized 8-week group MBSR treatment can significantly reduce symptoms of stress, anxiety and depression, and improve quality of life in at-risk mutation carriers for FTD. The primary objective is...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Neurological disorders congenital
Study type	Interventional

Summary

ID

NL-OMON48354

Source
ToetsingOnline

Brief title
MBSR in presymptomatic FTD

Condition

- Neurological disorders congenital
- Dementia and amnestic conditions

Synonym
frontotemporal dementia

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: ZonMw Memorabel,Bluefield

Project;Alzheimer Nederland;Dioraphte;AFTD

Intervention

Keyword: frontotemporal dementia, mindfulness-based stress reduction, presymptomatic, psychological burden

Outcome measures

Primary outcome

The primary outcome measure is the total, depression subscore (HADS-D) and anxiety subscore (HADS-A) of the HADS, developed to measure psychological distress in somatic patient populations (Zigmond & Snaith, 1983; Spinhoven et al., 1997; Norton et al., 2013). In short, it consists of a 7-item depression (HADS-D) and a 7-item anxiety (HADS-A) subscale. The HADS has good psychometric qualities in the general medical population (Bjelland et al., 2002). Internal consistency (Cronbach*s *) ranged between 0.84-0.90 (Spinhoven et al., 1997; Bjelland et al., 2002). Test-retest reliability was good (Pearson*s r >0.80) (Spinhoven et al., 1997).

Secondary outcome

The 36-item Short Form Health Survey (SF-36) assesses (health-related) quality of life across eight scaled domains: vitality, physical functioning, bodily pain, general health perceptions, physical role functioning, emotional role functioning, social role functioning and mental health (Ware & Sherbourne, 1992). The internal consistency (Cronbach*s *) (>0.85) as well as the test-retest reliability were good (Brazier et al., 1992).

The Utrecht Coping List (UCL) is a Dutch coping questionnaire, consisting of 47

items across seven subscales: seeking distraction, expression emotions, seeking social support, avoiding, fostering reassuring thoughts, passive coping, and active coping (Schreurs et al., 1984). The internal consistency (Cronbach*s *) ranged between 0.43-0.89 (Schreurs & van de Willige, 1988). The test-retest reliability ranged between 0.37 and 0.85 (Schreurs et al., 1993).

The Symptom Checklist 90 Revised (SCL-90-R) is a self-report questionnaire measuring a broad range of psychological problems and symptoms of psychopathology, including depression, anxiety, interpersonal sensitivity and somatization. It is also used in measuring the progress and outcome of psychiatric and psychological treatments or for research purposes (Arrindell & Ettema, 2005). Reliability and validity of this instrument were good (Derogatis & Savitz, 2000).

The Perceived Stress Scale (PSS) is one of the most widely used psychological instruments for measuring the perception of stress, both of stressful life events and current levels of experienced stress (Cohen et al., 1983). It has been used in previous studies assessing the effectiveness of stress-reducing interventions, including mindfulness (e.g. Marcus et al., 2003). The PSS showed adequate reliability and was correlated with life-event scores, depressive and physical symptomology, utilization of health services, and social anxiety (Cohen et al., 1983).

The 39-item Five Facet Mindfulness Questionnaire (FFMQ) measures mindfulness

skills across five subscales: observing, describing, acting with awareness, non-judging of inner experience, and non-reactivity to inner experience (Baer et al., 2008). The internal consistency (Cronbach*s *) ranged between 0.72 and 0.93, and the FFMQ proved to be sensitive to change in prior mindfulness-based interventions (Carmody et al., 2008).

Study description

Background summary

Frontotemporal dementia (FTD) is a young-onset type of dementia, with a clinically heterogeneous presentation of either behavioural disturbances (behavioural variant [bvFTD]) and/or language deterioration (Snowden, 2006). Because FTD has an autosomal dominant inheritance pattern in up to 40% we can define mutation carriers in the presymptomatic phase (Rabinovici, 2013). Mutations in the MAPT, GRN, and C9orf72 genes constitute the three most common causes of familial FTD (Warren, 2013). Familial forms constitute the ideal disease-model for FTD, as we can identify pathogenic mutation carriers in their presymptomatic stage and follow them longitudinally to develop sensitive biomarkers for e.g. pinpointing disease onset, tracking disease progression, and evaluating the effects of future disease-modifying treatments.

Started in 2009, a large cohort of at-risk mutation carriers are being followed in the Erasmus MC, called the FTD Risk Cohort (FTD-RisC). At present, only a minority of these persons have converted to the symptomatic phase. This means that a large number of persons lives with the knowledge of a 50% risk of carrying the pathogenic mutation for FTD. Moreover, these persons experience the onset and progression of FTD in at least one of their close relatives. Multiple participants have expressed feelings of distress, anxiety and depression related to the risk of developing FTD, and psychological treatment of these symptoms is therefore needed.

Some of the most promising clinical treatments for improving the quality of life for people with chronic illnesses are based on the concept of mindfulness. Mindfulness-Based Stress Reduction (MBSR) is defined as intentionally paying interceptive attention in the present moment in a non-judgmental way (Kabat-Zinn et al., 2004). MBSR has a variety of positive effects on both physical and psychological health, and has a beneficial effect on emotion regulation, with a significant improvement of symptoms of stress and mood disturbance in people with anxiety. There is increasing research evidence to

support the application of MBSR in patients with chronic diseases such as ALS (Pagnini et al., 2014), Parkinson*s Disease (Pickut et al., 2015) and epilepsy (Walker et al., 2010), however its effectiveness in (presymptomatic) FTD is so far unknown.

Study objective

The present study aims to investigate whether a standardized 8-week group MBSR treatment can significantly reduce symptoms of stress, anxiety and depression, and improve quality of life in at-risk mutation carriers for FTD. The primary objective is to investigate whether the MBSR programme is able to lower symptoms of anxiety and depression. The secondary objective is to investigate whether the MBSR programme is able to improve health-related quality of life and coping, and to decrease psychological problems, symptoms of psychopathology and stress.

Study design

The design of the study is a parallel group randomized controlled design. Participants are randomized between MBSR group and waitlist group. Randomization will be computerized using a randomization website. The waitlist group will get the opportunity to participate in the MBSR training afterwards as we would like to offer this programme to each at-risk participant. Baseline measurements will be administered after study inclusion, followed by randomization. After the MBSR programme in the intervention group or after 8 weeks in the waitlist group, post-measurements will take place, as well as a 2-months follow-up measurement. One year post-training, adherence to the programme will be investigated by means of a telephone follow-up. The exact setting of the study is to be determined, but will most likely take place outside of the hospital at a venue that is both centrally located and easily reachable by the study participants.

Intervention

A standardized 8-week group MBSR programme will be given to at-risk mutation carriers for FTD, in which participants are randomized between the intervention (MBSR) and waitlist (control) group. The control group can participate in the programme afterwards. The MBSR training is based on the 8-week programme developed by Kabat-Zinn (Kabat-Zinn et al, 2004) and is modified to fit our specific population of at-risk mutation carriers. The programme consists of 8 weekly 2.5 hour sessions, and home practice assignments of about 45 minutes, 6 days per week. Participants are provided with multimedia materials to guide their at home exercises and a folder with information and practice instructions. The MBSR training is taught by certified neuropsychologists with experience in (presymptomatic) FTD.

Study burden and risks

There are no known risks of undergoing a MBSR programme. The only burden to be expected is that from the relatively high time investment from each individual (8 times 2.5 hours programme, filling out questionnaires before and after the programme, and at 2-months follow-up). However, this potential burden is outweighed by the likely benefits of the programme in reducing anxiety, depression and distress in relation to FTD mutation carriership.

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

Asymptomatic, first-degree relatives of FTD patients due to genetic mutations (MAPT, GRN or

C9orf72 genes). They have 50% chance of having the mutation and therefore developing FTD. Age of 18 years and over.

Exclusion criteria

Symptomatic or participants suspect for developing FTD (Clinical Dementia Rating Scale > 0.5).
Persons with a previous or other (neurological) condition (e.g. stroke, brain tumour, MS) that may affect cognitive functioning to such a degree that it hampers study participation.
Current severe psychiatric conditions (e.g. clinical depression or anxiety disorders).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-11-2020
Enrollment:	26
Type:	Actual

Ethics review

Approved WMO

Date:	20-12-2019
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam

(Rotterdam)

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	NL68725.078.19