ISRCTN20615805 https://doi.org/10.1186/ISRCTN20615805

A feasibility study of Be Mindful

Submission date	Recruitment status	[_] Prospectively registered
12/09/2018	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/09/2018	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
10/07/2020	Other	

Plain English summary of protocol

Background and study aims:
Family carers (especially parents) of children and adults with intellectual disability (ID) are twice as likely as other carers to experience stress and mental health problems. There is no high quality research about effective and cost-effective ways to support parents. This study aims to find out if an online mindfulness course (Be Mindful) might help parents of children and adults with ID to look after their emotional well-being.

Who can participate?
Family carers (maternal or paternal caregivers) of children or adults of any age with ID who are living with their family carer(s)

What does the study involve?
Be Mindful is a 10-session course, and is an online version of the Mindfulness-Based Cognitive Therapy (MBCT) programme that is recommended in the NICE clinical guideline for depression (NICE, 2009). Thirty family carers will be randomly selected to receive Be Mindful, and 30 will receive Be Mindful plus telephone coaching support from trained parents who themselves have children with ID (Be Mindful+). All 60 family carers will be asked to complete some measures of things that might change after they have finished Be Mindful or Be Mindful+. The questionnaires will include questions about the family carers' well-being, the family carers' mental health, approaches to parenting, relationships with their partner (if they have one) and child with ID.

What are the possible benefits and risks of participating?
The Be Mindful programme has been successful in improving the well-being of participants who are not family carers of a child with learning disability. Because Be Mindful has not yet been tested with family carers who have a child with learning disability, we do not know yet if it will benefit participants. The questionnaires, Be Mindful programme, and additional telephone support sessions include positive things, but will also ask family carers to reflect on challenges they may face with their child. However, we do not think that taking part in the study will pose any risk to family carers or their children.

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

When is the study starting and how long is it expected to run for?
April 2018 to November 2019

Who is funding the study?
The Baily Thomas Charitable Fund (UK)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1

Study information

Scientific Title
Mindfulness Online STress intervention for family carers of children and adults with Intellectual Disability (MOST-ID): A feasibility study of Be Mindful.

Acronym
MOST-ID

Study objectives

To examine the feasibility of conducting a definitive trial of the BeMindful online mindfulness programme to reduce stress in parents of children or adults with intellectual disabilities

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Warwick Humanities and Social Science Research Ethics Committee (HSSREC), 09/02/2018, 58/17-18

Study design
Interventional randomised controlled feasibility study incorporating a process evaluation

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Internet/virtual

Study type(s)
Quality of life

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
Well-being in parents of children/adults with intellectual disabilities

Interventions
Parents will be randomised to receive BeMindful or BeMindful plus telephone coaching support (BeMindful+) on a 1:1 basis, using minimisation (via the free Minim randomisation programme) – balancing the age of the child with intellectual disabilities between the two arms of the trial (child under 10 years, child 10-18 years, adult >18 years).
BeMindful is an online mindfulness training programme. The course guides participants through all the elements of MBCT. Ten easy-to-follow online sessions, featuring videos and interactive exercises, are presented by qualified mindfulness trainers, and the course can be completed in as little as 4 weeks (although longer is typical). The course is highly accessible and can be followed from any device with a web browser and internet connection, such as mobile 'phones and tablets, including being saved as a web-app on the devices homepage. Twelve assignments to practise in daily life are included, along with six downloadable course hand-outs and online self-reporting tools to enable participants to chart progress with reducing stress, depression, and anxiety (measures different to those we propose to use as outcomes to ensure no overlap). Users also receive auto-generated supporting motivational emails.
Trained parent mentors will offer, arrange and deliver 3 guided support sessions for each of the 30 parents randomised to the BeMindful+ arm of the trial.

The intervention can be completed in 4 weeks, but most people take between 6 and 8 weeks to complete it. Recruitment will last for between 6 and 8 months from September 2018. The follow-up periods will be 12 weeks post-baseline and 6 months post-baseline.

Intervention Type
Behavioural

Primary outcome measure
Parent psychological well-being, assessed using the Warwick-Edinburgh Mental Well-Being Scale at the baseline, after 12 weeks and after 6 months.

Secondary outcome measures
The following will be assessed at the baseline, after 12 weeks and after 6 months:
1. Parental anxiety and depression, assessed using the Hospital Anxiety and Depression Scale (HADS)
2. Parental health-related quality of life, assessed using the EQ-5D-5L
3. Parent relationship with partner, assessed using:
3.1. Happiness of Relationship Scale
3.2. Disagreement over issues related to parenting/care of the child (from the Millennium Cohort Study Wave 2, 2003-2005)
4. Perception of family functioning/quality of life, assessed using the Family APGAR Scale
5. Parenting efficacy, assessed using 7 items from the Parenting Sense of Competence Scale (PSOC)
6. Parental perceptions of the positive impact of their child, assessed using the Positive Gain Scale
7. Parenting relationship, assessed using the Child-Parent Relationship Scale (CPRS)

Overall study start date
01/04/2018

Completion date
01/11/2019

Eligibility

Key inclusion criteria
Current inclusion criteria as of 23/10/2018:
Parents of children or adults of any age with intellectual disabilities who are living with their parent(s) for the majority of time (intellectual disabilities will be defined administratively, by parents reporting that the child or adult has received a diagnosis and/or is in receipt of UK learning disability services).

Previous inclusion criteria:
Parents of children or adults of any age with intellectual disabilities who are living with their parent(s) (intellectual disabilities will be defined administratively, by parents reporting that the child or adult has received a diagnosis and/or is in receipt of UK learning disability services)

Participant type(s)
Carer

Age group

Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

Total final enrolment
60

Key exclusion criteria
Parents concurrently receiving an individual or group therapy for stress, well-being, or mental health problems (including other mindfulness-based interventions).
We will gather information on parents' previous use of any mindfulness-based interventions, but this will not be an exclusion criterion.

Date of first enrolment
10/08/2018

Date of final enrolment
31/01/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Centre for Educational Development, Appraisal and Research (CEDAR)
New Education Building,
University of Warwick
Coventry
United Kingdom
CV4 7AL

Sponsor information

Organisation
University of Warwick

Sponsor details
University Road
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Sponsor type
University/education

Website
www.warwick.ac.uk

ROR
https://ror.org/01a77tt86

Funder(s)

Funder type
Not defined

Funder Name
Baily Thomas Charitable Fund

Alternative Name(s)
The Baily Thomas Charitable Fund

Funding Body Type
Private sector organisation

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

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The findings from the research will be published in high-impact, peer-reviewed journals.

Intention to publish date
01/01/2020

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2020	10/07/2020	Yes	No