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Randomised control trial of a digitally provided psychological intervention for people who have a gene for frontotemporal dementia or Alzheimer's disease in their family

Submission date
03/09/2024

Recruitment status
Recruiting

Registration date
12/09/2024

Overall study status
Ongoing

Last Edited
07/11/2025

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
Individuals who are at risk of rare familial dementias, specifically frontotemporal dementia (fFTD) and familial Alzheimer's disease (FAD) report struggling with guilt and anxiety about the risk to themselves and their children, decisions about whether to get tested, uncertainty about the onset of symptoms, and see their risk of potentially developing dementia as a barrier in life. Ongoing work suggests that these psychological difficulties also affect their ability to participate and remain in clinical drug trials, compromising the development of new treatments. Despite this there are currently no tailored interventions available to support people with the psychological consequences of living at risk of genetic dementias.
This study aims to determine the effectiveness of the IWARF blended in-person/online support programme in improving mental wellbeing for people living at risk of genetic dementias as well as understand people's experience of using this programme through interviews after they have used it.

Who can participate?
People aged 18 years and over with a first-degree relative who is symptomatic and/or a known mutation carrier for an inheritable form of dementia (either familial Alzheimer's disease [FAD] or familial Fronto-Temporal Dementia [fFTD])

What does the study involve?
Participants will complete some questionnaires and then be randomly allocated to use the online programme or to their usual care. Those assigned to the online programme will be invited to take part in an 8-week intervention comprising 10 online modules in 6 topic areas with additional psychoeducational videos and three video conference check-in sessions. Initially, participants will be shown an introductory video to demonstrate how to use the intervention and to explain the different features. Throughout the programme participants will have the option to contact the IWARF research team via email if they have any problems or queries. Participants will be invited to complete the modules that correspond to their needs, at their own

pace, with check-in sessions occurring at intervention-beginning, middle and end (facilitated by a Research Assistant or Research Fellow who will be trained/supervised by experienced Clinical Psychologists and researchers). Modules cover issues identified as important during the intervention development stages (e.g., rumination about risk or positive genetic status; uncertainty; making the most of life at risk; isolation). A mixture of materials will be used, including informational videos and independent activities, most drawing on Acceptance and Commitment Therapy (e.g., using mindfulness-based acceptance techniques to manage rumination).
All participants taking part will be invited to complete questionnaires again at ~9 weeks and 6 months after the start of the study, to understand if there has been greater change in their wellbeing after the intervention compared to usual treatment. Participants completing the online programme will also be invited to interviews about their experience.

What are the possible benefits and risks of participating?
This intervention is uniquely tailored to the needs of people living at risk of familial dementias. As a result, participants might feel better equipped to manage some of the practical and emotional aspects associated with living at risk of rare familial dementias. There are no clear risks to participation and should participants feel upset or distressed by any of the questions and /or content they will be able to discuss these in person with members of the research team during the check-in sessions built into the intervention.

Where is the study run from?
University College London (UCL) (UK)

When is the study starting and how long is it expected to run for?
March 2022 to March 2028

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
Prof. Joshua Stott, j.stott@ucl.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
NIHR203680

Study information

Scientific Title
Improving Wellbeing Associated with Rare Familial dementias (IWARF): an online support programme to improve psychological outcomes in people living at risk of inheriting either familial frontotemporal dementia or familial Alzheimer's disease

Acronym
IWARF

Study objectives
Current study objectives as of 07/11/2025:
Test the effectiveness of the IWARF intervention in improving wellbeing and psychological outcomes, and conduct a mixed methods process evaluation to elucidate mechanisms of change, barriers and facilitators to access and implementation as well as perceived benefits and costs. It is hypothesised that the Improving Wellbeing Associated with Rare Familial dementias (IWARF) online support programme may lead to improvements in a range of psychological outcomes (e. g., anxiety, depression, distress, wellbeing, quality of life etc) for people living at risk of inheriting either familial Fronto-Temporal Dementia (fFTD) or Familial Alzheimer's disease (FAD).

Previous study objectives:
It is hypothesised that the Improving Wellbeing Associated with Rare Familial dementias (IWARF) online support programme may lead to improvements in a range of psychological outcomes (e.g., anxiety, depression, distress, wellbeing, quality of life etc) for people living at risk of inheriting either familial Fronto-Temporal Dementia (fFTD) or Familial Alzheimer's disease (FAD)

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 10/01/2024, UCL Research Ethics Committee (University College London, 2 Taviton St, London, WC1E 6BT, United Kingdom; +44 (0)20 7679 8717; ethics@ucl.ac.uk), ref: 8545/008

Study design
Pragmatic single-blinded two-arm randomized controlled trial (with a nested internal pilot) and embedded process evaluation

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Familial dementias and specifically familial Fronto-Temporal Dementia (fFDT) and Familial Alzheimer's Disease (FAD)

Interventions
The aim of this study is to test the effectiveness of an online support programme (IWARF) via a randomised controlled trial (RCT) to improve a range of psychological outcomes for people living at risk of inheriting either fFTD or FAD. Specifically, this study will examine whether the online support programme is associated with improvements in wellbeing and reductions in depression and anxiety reductions in psychological inflexibility and experiential avoidance (theoretical tenets of Acceptance and Commitment Therapy) and improvements in overall quality of life and loneliness. The study has been designed as a two-arm RCT, whereby participants will be randomised to (1) the intervention group that will use IWARF, the online training and support programme, or (2) a waiting list control group who will access the rare dementia support website. In an embedded process evaluation, intervention participants will also be asked to complete a scale of system usability and be invited to an interview to discuss their experience. Randomisation will be provided via a secure online platform hosted by NWORTH CTU, Bangor University. Once consent and baseline measures have been completed participants will be entered into the randomisation system. A dynamic adaptive randomisation algorithm will be used to maintain the allocation ratio of 1:1 and balanced within stratification variables. Randomisation will be stratified by diagnosis (i.e., FAD, fFTD) and at-risk status (i.e. known mutation carrier, known non-carrier, unknown).

Participants assigned to the online programme will be invited to take part in an 8-week intervention comprising 10 online modules in 6 topic areas with additional psychoeducational videos and three video conference check-in sessions. Initially, participants will be shown an introductory video to demonstrate how to use the intervention and to explain the different features. Throughout the programme participants will have the option to contact the IWARF research team via email if they have any problems or queries.

Participants will be invited to complete the modules that correspond to their needs, at their own pace, with check-in sessions occurring at intervention-beginning, middle and end (facilitated by a Research Assistant or Research Fellow who will be trained/supervised by experienced Clinical Psychologists and researchers). Modules cover issues identified as important during the intervention development stages (e.g., rumination about risk or positive genetic status; uncertainty; making the most of life at risk; isolation). A mixture of materials will be used, including informational videos and independent activities, most drawing on Acceptance and Commitment Therapy (e.g., using mindfulness-based acceptance techniques to manage rumination).

All participants taking part will be invited to complete questionnaires again at ~9 weeks and 6 months after the start of the study, to understand if there has been greater change in their wellbeing after the intervention compared to usual treatment. Participants completing the online programme will also be invited to interviews about their experience.

Intervention Type
Behavioural

Primary outcome(s)
Current primary outcome measure as of 07/11/2025:
Overall mental wellbeing assessed using the 14-item Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS) at T0 (baseline), T1 (~9 weeks after baseline), and T2 (follow-up at 6 months after baseline)

Previous primary outcome measure:
Overall mental wellbeing assessed using the 14-item Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS) at T0 (baseline), T1 (~8 weeks after baseline), and T2 (follow-up at 6 months after baseline)

Key secondary outcome(s))
Measured at T0, T1 and T2:
1. Anxiety measured using the General Anxiety Disorder 7-item scale (GAD7)
2. Depression measured using the Patient Health Questionnaire 9-item scale (PHQ9)
3. Feelings related to genetic risk/predictive testing measured using an adapted version of the 26-item Psychological Adaptation to Genetic Information Scale (PAGIS)
4. Health-related quality of life measured using the European Quality of Life 5 Dimensions 5 level version (EQ-5D-5L)
5. Quality of life and capability wellbeing measured using the ICEpop CAPability for Adults 5-item scale (ICECAP-A)
6. Loneliness measured using the Office for National Statistics loneliness measure comprised of the UCL 3-item loneliness measure with additional subjective loneliness question
7. Acceptance and Commitment Therapy (ACT) based skills, and primarily psychological flexibility measured using the 24-item Multidimensional Psychological Flexibility Inventory (MPFI-24)
8. Health and social care resource use measured using a bespoke health economics measure, AR-RUM, developed for the purposes of the trial
9. The usability of the website will be evaluated using the System Usability Scale (SUS) at T1 only and only in the intervention group (it forms part of the process evaluation)

Completion date
31/03/2028

Eligibility

Key inclusion criteria
1. Aged 18+ years with a first-degree relative who is symptomatic and/or a known mutation carrier for an inheritable form of dementia (either familial Alzheimer’s disease [FAD] or familial Fronto-Temporal Dementia [fFTD])
2. Capacity to consent to research
3. Access to an internet-enabled device

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Individual is below the age of 18 years
2. Individual does not have a first-degree relative who is symptomatic and/or a known mutation carrier
3. Individual reports to the trial team to be displaying symptoms of FAD/fFTD before enrollment
4. Individual does not have capacity to consent to research
5. Individual does not have access to an internet-enabled device

Date of first enrolment
01/10/2024

Date of final enrolment
01/03/2027

Locations

Countries of recruitment
United Kingdom

England

Wales

Study participating centre
University College London
Division of Psychology & Language Sciences (PaLS)
1-19 Torrington Place
London
United Kingdom
WC1E 7HB

Study participating centre
University College London
Dementia Research Centre
8-11 Queen Square
London
United Kingdom
WC1N 3AR

Study participating centre
Bangor University
NWORTH CTU
College of Medicine and Health
Bangor
United Kingdom
LL57 2PZ

Study participating centre
Swansea University
Centre for Ageing and Dementia Research
Talbot Building
Singleton Campus
Swansea
United Kingdom
SA2 8PP

Sponsor information

Organisation
University College London

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Data will be stored in a non-publically available repository (UCL Data safe haven).

IPD sharing plan summary
Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet version 2	11/11/2025	11/11/2025	No	Yes
Protocol file		17/10/2024	21/10/2024	No	No