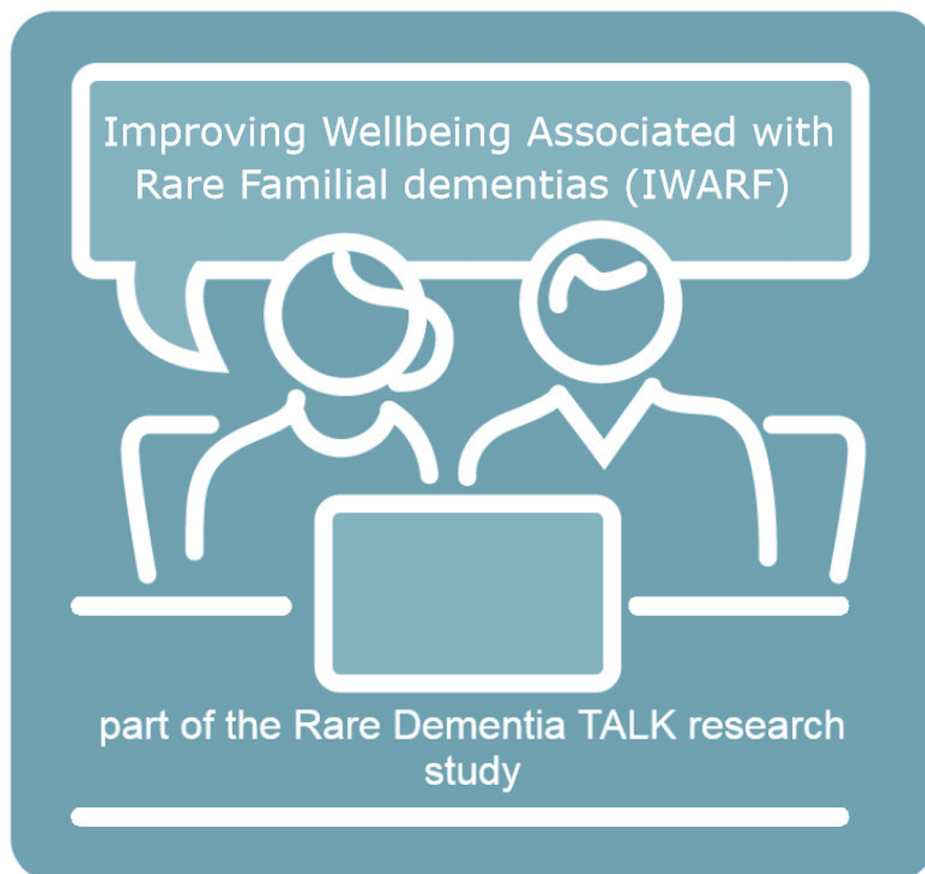
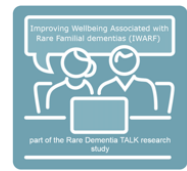


Improving Wellbeing Associated with Rare Familial dementias (IWARF): Randomised Controlled Trial Information Sheet



We would like to invite you to take part in a randomised controlled trial. The trial is investigating whether a new support programme called “Improving Wellbeing Associated with Rare Familial dementias (IWARF)” is better at helping support you as a member of a family with an inheritable form of dementia compared to an already-available website. The trial is part of a large research study called Rare Dementia TALK, which is a collaboration between UCL, Bangor University, Swansea University and King’s College London.



Why is this study important?

Your experience is relatively rare, and may differ depending on whether you do not know your genetic status, have found out you carry the gene, or are gene negative. This means tailored support resources for you and your family members are scarce. Being a member of a family with an inheritable dementia can be very difficult and many family members in this position experience more mental health problems and physical illness compared to people whose families have not been impacted by an inheritable form of dementia. If we show that “Improving Wellbeing Associated with Rare Familial dementias (IWARF)” helps people like you, who are a member of a family with a known inheritable form of dementia, then service providers will benefit by knowing there is a proven service they can recommend to other people who may be going through a similar experience.

Why have I been invited to take part?

We are inviting you to take part because you are aged 18 or over and have self-identified as someone who is either: a member of a family with an identified genetic risk of either familial Frontotemporal dementia (fFTD) or familial Alzheimer’s disease (FAD) (not tested); a person who has found out they carry the fFTD/FAD gene (gene-positive), or have taken a genetic test which has come back negative for the fFTD/FAD gene (gene-negative). We plan to invite 118 people to take part in this study. You do not have to travel anywhere to take part. Everything will take place via an online platform, so you can do this research study from your own home.

Do I have to take part?

Taking part in this study is voluntary. If you do decide to take part, we will send you a link where you can indicate your consent to responding to some questions to find out if the study is right for you. If it is, you will be taken to a survey page which will ask you to consent to the study via filling in a short online form.

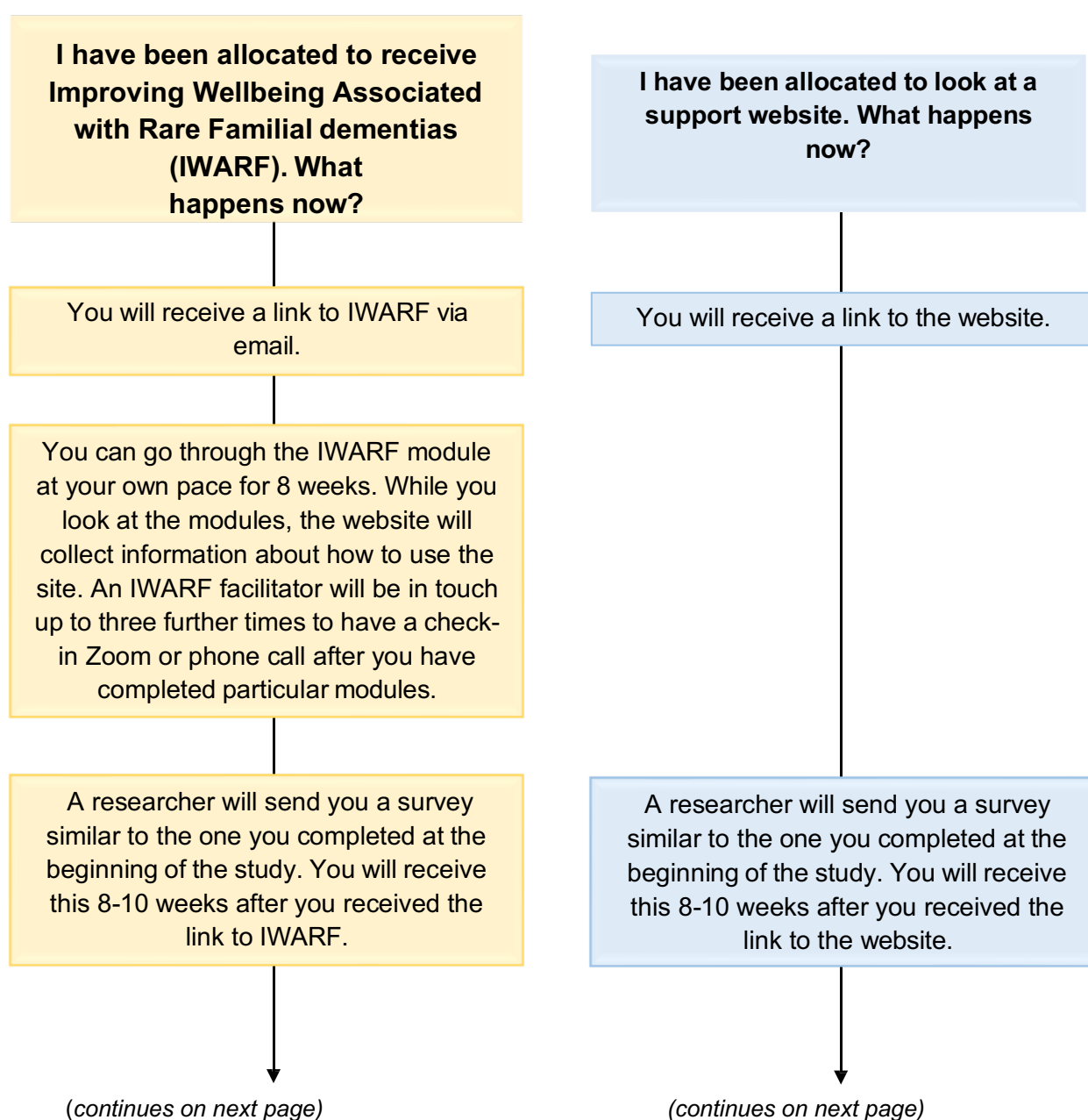
If you change your mind after agreeing to take part, you can withdraw at any time and you do not have to say why. Withdrawing from the study will not make any difference to your health care or support received, and it will not affect your rights in any way. As standard in other research studies, we will keep the data we have collected up until the point you withdraw from the study.

What will happen if I decide to take part?

You will receive a link to an online survey asking you about your role as a member of a family with an inheritable form of dementia. This online survey will help us to understand your situation and if this study is right for you. There’s a chance the study may not be the right fit for you, in which case you will see a message letting you know this, and encouraging you to continue to access Rare Dementia Support resources as normal.

If the study is the right fit for you, you will be guided to the next part of the survey, which will seek your consent to taking part in the study via an embedded consent form. If you consent to taking part, you will then be asked a series of questions via the same online survey. Once we have received your responses to these questions, we will allocate you to either receive “Improving Wellbeing Associated with Rare Familial dementias (IWARF)” for an 8- week period, or be pointed to an already available website.

This flowchart will guide you through the steps of what would happen next, depending on which group you are allocated to.





A researcher will send you a final survey, 6 months after you received the link to IWARF.

A smaller number of people taking part in the study will also be asked to take part in a more in-depth interview with a member of the research team who will ask more open questions about your experiences of using Improving Wellbeing Associated with Rare Familial dementias (IWARF). This will help us understand which aspects of the “Improving Wellbeing Associated with Rare Familial dementias (IWARF)” programme help people the most or which might be more challenging, so we can improve it for future use.

A researcher will send you a final survey, 6 months after you received the link to the website.

Once the research team have received your responses, the researcher will give you access to Improving Wellbeing Associated with Rare Familial dementias (IWARF).

If you are invited to be enrolled in the trial, you will receive a £15 voucher as a token of our appreciation for your participation.

What are the possible benefits of taking part?

This program is tailored to support these different experiences. You (and other members of your family who may be in a different situation to you) may therefore benefit from IWARF by feeling better-equipped to handle some of the practical and emotional aspects that are associated with being a member of a family impacted by an inheritable form of dementia.

What are the possible disadvantages and risks of taking part?

We do not think that taking part will involve any disadvantages or any specific risks to you or that it could cause you any harm. If you do find any questions upsetting or distressing, you do not have to answer them, and the researcher will be sensitive and supportive of your situation.

What if something goes wrong

If you are unhappy or dissatisfied about any aspect of your participation, we would ask you to please tell us about this straight away, so that we can try to resolve any concerns and find a solution. If you have any cause to complain about how you have been approached or treated during this study, please contact the Lead Investigator Prof. Joshua Stott: j.stott@ucl.ac.uk and/or UCL Research Ethics Committee Chair ethics@ucl.ac.uk

How is the study organised and funded?

The research is led by University College London and funded by the National Institute



for Health and Care Research (NIHR).

Will my taking part in the study be kept confidential?

All information that is generated during the course of the trial (e.g. your answers to questions) will be stored securely and will be kept separate from any of your personal details. No-one outside the research team will be able to identify you personally from these records. The information you give us will be 'pseudonymised'; this means that a unique identifying code will be used to link your research data with your personal details. We won't use any recognisable information such as your name or any other personal information in reports or publications; this means your data will be 'de-identified' for any publication purposes.

The information that we collect about you during the course of the study will be treated as confidential. The only situation in which we might need to share information about you with other professionals would be if the researchers observe or hear anything that causes very serious concern about your health, safety or well-being, or that of another person. If this happens the researchers have a duty to inform an appropriate professional, and will contact the lead investigator of this study in the first instance.

It is a requirement from our research funder that we keep the information we have collected as part of the study in secure, longer-term storage. In addition, at the end of the study we are required by our research funder to add the information we collect as part of the trial process into a data archive such as the UK Data Archive. The information stored would have identifying features (e.g. names) redacted, so no-one would ever be able to identify you personally from this information. The motivation to do this is so other researchers may do different types of analysis on the information we collect in the future.

If you are invited to take part in the additional interview, there is a separate information sheet and consent process relating to the data we will collect as part of this. We will share this with you in the event we invite you to take part.

What will happen if I change my mind about taking part?

You can withdraw from the study at any time without giving a reason. If you withdraw from the study it will not affect your health care, support provisions, or legal rights in any way. We will continue to use the information collected before you decided to withdraw.

What will happen to the results of the research study?

We want our work to make a difference and help people who have a family with a known inheritable form of dementia. We will publish the results in scientific journals, present them at academic, health and care professionals' conferences, promote the main highlights through social media, and prepare short summaries for health and care professionals/organisations. In addition, we will create summaries of our findings which



we will share with you and other people who have a similar lived experience to you.

Who has reviewed the study?

All research is first reviewed by an independent group of people called a Research Ethics Committee, to protect your interests, safety, rights, well-being and dignity. This study has been reviewed and approved by the UCL Research Ethics Committee, University College London (AEC number: 8545/008).

Who can I contact for further information?

For more information, please contact our trial team via email: iwarf@ucl.ac.uk

UCL DATA PROTECTION PRIVACY NOTICE (THE TECHNICAL BITS)

The controller for this project will be University College London (UCL). The UCL Data Protection Officer provides oversight of UCL activities involving the processing of personal data, and can be contacted at data-protection@ucl.ac.uk

This 'local' privacy notice sets out the information that applies to this particular study. Further information on how UCL uses participant information can be found in our 'general' privacy notice:

For participants in health and care research studies, click [here](#)

The information that is required to be provided to participants under data protection legislation (GDPR and DPA 2018) is provided across both the 'local' and 'general' privacy notices.

The lawful basis that will be used to process your personal data is: 'public task' and 'research purposes' will be the lawful basis for processing special category data.

Your personal data will be processed so long as it is required for the research project. If we are able to anonymise or pseudonymise the personal data you provide we will undertake this and will endeavour to minimise the processing of personal data wherever possible.

If you are concerned about how your personal data is being processed, or if you would like to contact us about your rights, please contact UCL in the first instance at data-protection@ucl.ac.uk