

Comparing mental well-being of people with hearing loss who have been partnered with a hearing dog to those that have applied for, but not yet received a hearing dog

Submission date 28/01/2019	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 06/02/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 27/03/2023	Condition category Ear, Nose and Throat	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Over 10 million adults in the UK have a hearing impairment. One in every hundred adults is severely or profoundly deaf and, for these individuals, it is highly unlikely that medical interventions to address hearing loss (e.g. hearing aids, cochlear implants) will have any benefit. Some people are born with no or impaired hearing, or develop it in childhood. For others, hearing loss is acquired during adulthood or old age. Research suggests it is harder to adapt to acquired hearing loss as an adult or older person. People with hearing impairments do not fare as well as the general population in many areas of their lives including employment, independence, social inclusion, well-being and mental health. Some people with hearing impairments will be eligible for support from local authority services, such as Sensory Impairment Teams. However, the support available is often limited and/or restricted to a fixed number of sessions or duration.

Hearing Dogs for Deaf People (HDfDP) was set up in 1982. To start, HDfDP believed that a dog's ability act as 'proxy ears' for their 'human partner' was the predominant way in which a hearing dog supported individuals with a severe or profound hearing impairment. However, accounts of improvements in mental well-being, quality of life, social and economic participation and independence - and which were being attributed to having a hearing dog - suggested that hearing dogs could have a much wider impact. As a result HDfDP now identifies the practical assistance and emotional support which a hearing dog partnership can offer. To date, HDfDP has created over 2000 hearing dog partnerships. However, there has been very little research into their impact. Indeed, we have only managed to identify two studies which specifically investigated and evaluated hearing dogs partnerships, one of which was carried out in the US. Importantly, the design of these studies meant they could not reliably answer questions about the impacts and outcomes of having a hearing dog.

This study will use different research methods to investigate and test the impacts, cost-effectiveness and experiences of hearing dog partnerships. First, the study looks at whether having a hearing dog impacts on people's well-being and other outcomes, such as mental health, and work and social functioning. Second, the study investigates whether hearing dog

partnerships are cost-effective in terms of the costs and benefits to statutory services, individuals and wider society. Third, people who have hearing dogs and staff who work for HDfDP are interviewed to explore how and why having a hearing dog may affect and change people's lives. Finally, the study will explore how staff working in Local Authority Sensory Impairment Teams understand hearing dog partnerships and their views and experiences of working with people in a hearing dog partnership and/or HDfDP as an organisation.

Who can participate?

Adults aged 18 with severe or profound hearing loss, living in the United Kingdom, who meet the criteria to be eligible to apply for their first hearing dog

What does the study involve?

The study involves hearing dog applicants being invited to complete up to six questionnaires whilst they are waiting for and once they have received their hearing dog. The questionnaires include a number of standardised measures to capture their mental and physical health and well-being and the problems they experience which can be associated with hearing loss. Participants also provide information about the services they use to inform the economic evaluation.

What are the possible benefits and risks of participating?

Participants in the 'fast-track' group may receive a hearing dog sooner than they might have. There are no other direct benefits to participation. All participants will receive a hearing dog within the maximum time limit which HDfDP sets for matching any applicant with a hearing dog. Some individuals with hearing loss/born deaf have low levels of English literacy or British Sign Language is their main or preferred form of communication. There is a risk, therefore, that information about study participation and the content of the Research Questionnaire will not be accessible to all potential participants if presented solely in usual English text. To this end, the researchers have created an additional plain English version of the Study Information Sheet, and a BSL version (viewable on the project's webpage) is currently being created. A BSL version of the Research Questionnaire (completed on-line) is also being created (BSL versions of most of the standardised outcome measures are already available).

Hearing Dog for Deaf People has extensive experience of determining applicants' literacy support needs during their initial contacts with applicants. This will guide decisions regarding the format of materials sent to potential participants. Participants will be advised that alternative formats of the Research Questionnaire are available.

There is a risk that a potential participant does not properly understand 'randomisation'. The researchers have taken care in all project information to offer a clear explanation of this concept and the difference between the two trial groups ('fast-track matching timeline' vs 'usual matching timeline'). The Study Information Sheet makes a clear offer regarding contacting the research team with any queries/to discuss participation. This will be reiterated in the follow-up contact made ~7 days after potential participants have received the Study Recruitment Pack. There is a risk that potential participants may believe that not participating in the study will jeopardise their application or result in a longer wait for a hearing dog. The Study Information Sheet makes clear that participating, or not, in the study will not affect their application in any way. For those not wishing to participate in the trial, their application will be processed in the usual way and against usual timelines for HDfDP.

Equally, others may believe that participation will somehow advantage their application. Whilst participation in the trial means an individual may be allocated to the 'fast-track timeline' group, allocation to this arm is by chance. Furthermore, all study participants will be matched with a hearing dog within the maximum time limit which Hearing Dogs for Deaf People works to (2.5 years from acceptance of application to match with a hearing dog). Again, this information is clearly set out in the Study Information Sheet.

Where is the study run from?
Hearing Dogs for Deaf People (UK)

When is the study starting and how long is it expected to run for?
October 2016 to March 2020

Who is funding the study?
NIHR School for Social Care Research (UK)

Who is the main contact?
Prof. Bryony Beresford
bryony.beresford@york.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Bryony Beresford

ORCID ID
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
C088/CM/UYYB-P111

Study information

Scientific Title
A randomised controlled trial investigating the impact of receiving a hearing dog on recipient well-being

Acronym

PEDRO

Study objectives

Receipt of a hearing dog improves mental well-being, quality of life, social and economic participation and independence (compared to no dog/no intervention).

Ethics approval required

Old ethics approval format

Ethics approval(s)

University of York Social Policy and Social Work Ethics Board, The University of York, York, YO10 5DD, Tel: +44 (0)1904 321297, Email: mark.wilberforce@york.ac.uk, 03/02/2017, ref: SPSW/S/17/1

Study design

Single-centre pragmatic trial with a nested longitudinal cohort study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Home

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

Hearing loss

Interventions

The randomisation is being conducted centrally by York Trials Unit. Block randomisation, with a block size of 2, is being used to allocate participants 1:1 to either arm A or arm B. The allocation schedule was generated in Stata v15 by a statistician at York Trials Unit. A pair of participants are randomised together by being assigned to the next available block of two allocations.

Intervention: partnership with a hearing dog

Comparator: no hearing dog

As the intervention is receipt of a hearing dog, the duration is for as long as the placement remains intact. In the case of a successful partnership, this would be until the hearing dog retires at ~11 years of age. The recipient would then be eligible to apply for a successor dog.

Follow-up for the study is as following:

T1 - 6 months post-receipt of dog (intervention arm) plus comparator (no dog) arm

T2 - 12 months post-receipt of dog (intervention arm) plus comparator (no dog) arm* *only if applicant in this arm still does not have a dog

T3 - 18 months post-receipt of dog (those who have received dog only)

T4 - 24 months post-receipt of dog (those who have received dog only)

The main comparative element of the trial is at T1. Comparisons at T2 are only where the participants in the comparator arm still have not received their dog. T3 and T4 are longer term follow ups just of those who have received a dog.

Intervention Type

Other

Primary outcome measure

Mental wellbeing measured using the Short Warwick Edinburgh Mental Well-being Scale at the following timepoints:

T0-1 (Baseline) acceptance of application by Hearing Dogs for Deaf People

T0 Point of randomisation

T1 Primary timepoint: Six months' post-receipt of hearing dog - comparator no dog

T2 12 months' post receipt of hearing dog - comparator no dog (where applicable)

T3 18 months' post receipt of hearing dog. Intervention arm only

T4 24 months' post receipt of hearing dog. Intervention arm only

Secondary outcome measures

All secondary outcomes are being collected at the same time points as the primary outcomes. (T0-1 on application to Hearing Dogs for Deaf People, T0 on randomisation, T1 6 months after Arm B participant has received dog, T2 12 months after Arm B participant has received dog, T3 18 months after Arm B participant has received dog, T4 24 months after Arm B participant has received dog). Only participants who received their dog before July 2018 will be eligible to receive T3/T4 questionnaires).

1. Quality of Life measured using EQ5D

2. Anxiety measured using GAD7

3. Depression measured using PHQ9

4. Impairment in functioning using WSAS

5. Problems associated with hearing impairment which a hearing dog is meant to alleviate, measured using the Hearing Dog Questionnaire

Overall study start date

01/10/2016

Completion date

30/03/2020

Eligibility

Key inclusion criteria

1. Any adult aged 18 living in the United Kingdom who meets the criteria to be eligible to apply for their first hearing dog

2. They must have severe or profound hearing loss

Participant type(s)

Other

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

162

Total final enrolment

213

Key exclusion criteria

1. Individuals who do not reach the criteria to be eligible for a hearing dog
2. Individuals aged 17 yrs or younger
3. Individuals requiring a dog who can provide sound and vision support
4. Individuals who are replacing a retiring hearing dog or have already had a hearing dog
5. Individuals with learning disability (indicated by use of proxy during application process)

Date of first enrolment

01/04/2017

Date of final enrolment

31/03/2018

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre**Hearing Dogs for Deaf People**

The Grange

Wycombe Road

Saunderton

Princes Risborough

United Kingdom

HP27 9NS

Sponsor information

Organisation

University of York

Sponsor details

University of York

York

England

United Kingdom

YO10 5DD

Sponsor type

University/education

ROR

<https://ror.org/04m01e293>

Funder(s)

Funder type

Government

Funder Name

School for Social Care Research

Alternative Name(s)

NIHR School for Social Care Research, SSCR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

The trialists are in the process of updating the SAP and preparing the protocol for publication. They will be writing a report for the funder (School for Social Care Research) and plan to publish their findings in a high-impact peer reviewed journal.

Intention to publish date

30/03/2021

Individual participant data (IPD) sharing plan

Requests for access to anonymised data should be sent to the study PI, Professor Bryony Beresford (bryony.beresford@york.ac.uk). Questionnaire data is anonymised and entered onto SPSS 25. This anonymised data can be made available upon completion of the project which is Spring 2020. The data will be stored for 10 years, in line with University of York and SSCR policies. Participants have not explicitly consented for their data to be shared. Research data is anonymised and stored separately to participant contact data. Participants have a unique ID code.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	17/04/2020	20/04/2020	Yes	No
Results article		14/10/2021	27/03/2023	Yes	No