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Optimising access to vocational rehabilitation through multiple sclerosis charities: A feasibility randomised controlled trial
(MS Work Hub Study)

PARTICIPANT WITH MS INFORMATION SHEET

Research Ethics Reference: FMHS 102-0325
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We would like to invite you to take part in a research study about supporting people with multiple sclerosis (MS) to remain in paid employment. Before you decide, it is important for you to understand why the research is being done and what it will involve. A member of our team will go through the information sheet with you and answer any questions you have. Please take time to read this carefully and discuss it with others if you wish. Ask us anything that is not clear.

What is the purpose of this study?

MS can sometimes negatively impact employment. Some people decide to leave work sooner than intended because of the challenges of working with MS. Some of the reasons why people with MS leave employment are related to their MS, the demands of the job, and/or working environment.

Vocational rehabilitation aims to help people with illness or disability to remain at work, return to work, or retire from work at an appropriate time. Vocational rehabilitation could help people with MS to make informed decisions about employment and support them at work. However, few such services are currently available for people with MS in the UK.

We have previously developed a job retention vocational rehabilitation (called MSVR) intervention for people with MS. We have tested this intervention in the community (e.g., outside of a hospital) and in the NHS. Participants from previous studies have suggested that charities supporting people with MS to live well could offer this support.

This study aims to evaluate the feasibility of incorporating a job retention vocational rehabilitation intervention for people with MS within existing MS charity services. It will help us understand how this support can be integrated into MS charity services and what helps people with MS remain at work.

Why have I been invited?

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You have been invited because you have MS, are over 18 years old, and are currently in paid employment (including self-employed). We would like to understand your work situation and offer you information and advice tailored to your employment circumstances.

Do I have to take part?

It is up to you to decide if you want to take part in this research. We will describe the study and go through this information sheet with you to answer any questions you may have. If you agree to participate, we will ask you to sign a consent form and will give you a copy to keep. However, you would still be free to withdraw from the study at any time, without giving a reason, simply let the research team know.

What will I be asked to do?

A researcher will contact you to review the information sheet, explain the procedures, and go through a pre-screening checklist to check if you are eligible to participate. If you are still happy to take part, then you will then be asked to sign a consent form.

If you choose to take part, you will be asked to complete a booklet of questionnaires (approximately 30 minutes). After completing the questionnaire, you will be randomly assigned to one of two groups (MSVR support or control group). The allocation is 1:1, meaning 50% of participants will receive support with employment, and 50% of participants will receive the usual services from the participating MS charities. The allocation is random, and neither the researcher nor workers from MS charities will know which group you will be assigned to at the time of recruitment.

Once you have been allocated to a group, we will inform you via email. If you are allocated to the control group, you will continue to receive the usual support that MS charities provide, and we will contact you after six months to complete a questionnaire and ask you some questions about your experiences of being in the control group.

If you are allocated to the MSVR group, a member of the MS charity will contact you to offer you advice and/or support with employment. The first step will involve an initial appointment to discuss your employment and agree what you would like to achieve with the support. This appointment should last approximately one hour.

Following the interview, you will be offered between 1 to 10 hours of support from an MSVR champion (i.e., employee from MS charity) to discuss topics that may be useful for you (e.g., legal rights at work, support identifying reasonable adjustments, managing memory at work, etc). This will be spaced out over six months. You may not need all the hours of support.

During the six months, you can book sessions remotely by telephone or videoconference to address topics relevant to you (e.g., how to tell your employer you have MS, support identifying reasonable adjustments, managing memory at work, etc). The frequency and length of the sessions will depend on your needs and preferences. We estimate that each appointment may last up to one hour.

At the end of the six months, you will be asked to complete another booklet of questionnaires, and some participants will be contacted for an interview with a member of the research team to provide feedback about your experiences of being involved in the study. All interviews will be audio-recorded and transcribed verbatim (word-for-word) by the automated transcription service of the University of Nottingham. We will ask those interested in participating in the interview via Microsoft Teams if we can video-record the session using the “record” option of Microsoft Teams. This option allows you to record the discussions with a greater quality of

audio, and you can choose to have the camera off if you prefer. The audio and video recordings will be destroyed once they have been transcribed. The data we collect during the study will be stored for seven years.

The table below shows the maximum amount of time you will be involved in the study.

Table 1: What does the study involve?

Task	MSVR Group	Control group
Screening and initial questionnaires	30 minutes	30 minutes
Initial interview	1 hour	-
Support with employment	Between 1 to 10 hours	-
Completion of questionnaires at the end of the study	30 minutes	30 minutes
Optional interview	30 minutes	30 minutes
Completion of questionnaires after 3 months	30 minutes	30 minutes
Completion of questionnaires after 6 months	30 minutes	30 minutes
Total Approximate Time	**13.5 hours**	**2.5 hours**

During the screening, you will be asked if you want to include your employer in the study. Our research identified that informing the employer about MS and educating them about how they can support an employee with MS at work can benefit the person with MS. **Involving your employer is optional, and you have the right to deny their involvement.** Furthermore, the content of the discussions in this study is confidential, even if you decide to include your employer.

Are there any risks in taking part?

We do not anticipate that taking part in this study will cause you any harm or risk. However, taking part in this study will take some of your time.

If you feel upset or tired during any of the sessions, you can share your concerns with the researcher to stop the session if you wish. We will check with you whether you are ok and willing to continue with the study. Again, you are welcome to leave the study at any time.

Are there any benefits in taking part?

We cannot promise the study will help you personally, but the information we get from this study may help us improve the vocational rehabilitation services available to people with MS in the UK.

Will my time/travel costs be reimbursed?

Participants will be offered a £20 voucher as a token of gratitude for their involvement in the research if they complete the study questionnaires. The study has been designed to be completed remotely. Therefore, no travel expenses will be incurred.

What happens to the data provided?

The research data will be stored confidentially. To help ensure your privacy, you will be assigned a volunteer study identification number (for example P01 for participant number 1), and it will be used instead of your name. We would like your permission to use fully

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anonymised direct quotes in research publications. The transcripts will be anonymised, and we will use a pseudonym for any names of people or places you mention during the interview or group discussion. Your name and any information about you will not be disclosed outside the study centre. The video/audio recordings will be uploaded into a password-protected database and they will be deleted after we transcribe the interviews. Only the research team will have access to the full transcripts from the study.

All research data and records will be stored for a minimum of 7 years after publication or public release of the work of the research. We would like your permission to use anonymised data in future studies and to share our research data (e.g., in online databases) with other researchers in other Universities and organisations both inside and outside the European Union. This would be used for research in health and social care. Sharing research data is important to allow peer scrutiny, re-use (and therefore avoiding duplication of research) and to understand the bigger picture in particular areas of research. All personal information that could identify you will be removed or changed before the information is shared with other researchers or results are made public. Data sharing in this way is usually anonymised (so that you could not be identified)

What will happen if I don't want to carry on with the study?

Even after you have signed the consent form, you are free to withdraw from the study at any time without giving any reason. Any personal data will be destroyed. You can opt to stop your involvement in the study at any time by telling the researcher that you are no longer interested in carrying out the research. If you withdraw from the study, we will no longer collect any information about you or from you, but we will keep the anonymised research data that has already been collected and stored as we are not allowed to tamper with study records. This information may have already been used in some analyses and may still be used in the final study analyses.

Who will know that I am taking part in this research?

Data will be used for research purposes only and in accordance with the General Data Protection Regulations. Any video/audio digital recordings and electronic data will be anonymised with a code as detailed above. Electronic storage devices will be encrypted while transferring and saving of all sensitive data generated during the research. All such data are kept on password-protected databases sitting on a restricted access computer system and any paper information (such as your consent form, contact details and any research questionnaires) would be stored safely in lockable cabinets in a swipe-card secured building and would only be accessed by the research team.
Under UK Data Protection laws the University is the Data Controller (legally responsible for the data security) and the Chief Investigator of this study (named above) is the Data Custodian (manages access to the data).

You can find out more about how we use your personal information and read our privacy notice at: https://www.nottingham.ac.uk/utilities/privacy.aspx/

Designated individuals of the University of Nottingham may be given access to data for monitoring and/or audit of the study to ensure we are complying with guidelines. With your consent, we will keep your personal information on a secure database to contact you for future studies.

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Anything you say during an study will be kept confidential unless you reveal something of concern that may put yourself or anyone else at risk. It will then be necessary to report to the appropriate persons.

What will happen to the results of the research?

The findings of the study may be published in relevant scientific journals, presented in conferences to scientific audiences, and presented to people with MS and relevant stakeholders. If you decide to take part in this research and are interested in knowing the results, please, let us know and we will send you a summary.

Who has reviewed this study?

All research involving people is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests.

Who is organising and funding the research?

This research is being organised by Dr Blanca de Dios Perez at the University of Nottingham and is being funded by the MS Society.

What if there is a problem?

If you have a concern about any aspect of this project, please speak to the principal investigator and lead researcher Dr Blanca De Dios Perez, who will do their best to answer your query. The researcher should acknowledge your concern and give you an indication of how she intends to deal with it. If you remain unhappy and wish to complain formally, you can do this by contacting the FMHS Research Ethics Committee Administrator, Faculty Hub, Medicine and Health Sciences, E41, E Floor, Medical School, Queen's Medical Centre Campus, Nottingham University Hospitals, Nottingham, NG7 2UH or via E-mail: FMHS-ResearchEthics@nottingham.ac.uk.
Please quote ref no: FMHS 102-0325

Contact details
Should you require further information about the study, please contact Dr Blanca De Dios Perez at blanca.dediosperez@nottingham.ac.uk

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