Dr Melanie Fleming
sleep-win@ndcn.ox.ac.uk

PARTICIPANT INFORMATION SHEET

IRAS ID: 3062941, Ethics Ref: 22/EM/0080
Version 1.4, 06Dec2022

Study Title: Improving sleep and learning in rehabilitation after stroke (INSPIRES-2)

We would like to invite you to take part in our research study. Before you decide, it is important that you understand why the research is being done and what it would involve for you. Please take time to read this information, and discuss it with others if you wish.
If there is anything that is not clear, or if you would like more information, please ask us.

What is the purpose of the study?

Sleep is important for learning new movements and skills. Sleep is often worse after stroke and so we want to test for improvements in sleep with an online cognitive behavioural therapy insomnia programme called Sleepio. We also want to test whether improving sleep impacts on movement learning.

Why have I been invited?

You have been invited because you have had a stroke which has affected the movement of your hand or arm, you experience sleep problems and would like to access ways to improve your sleep. We are looking to include up to 100 stroke survivors in this study.

Do I have to take part?

No. Taking part is voluntary.
If you choose to take part you are free to withdraw at any time, without giving a reason. Any decision to participate, or not, will not affect your clinical/rehabilitation care.

What will happen to me if I decide to take part?

In addition to routine care, there are 4 steps to this study. All steps take part in your home. There is no need to visit the University.

Step 1

- If you would like to take part, then we will discuss the study with you and then ask you to complete a consent form, either online or we will go through the consent form with you on the phone and ask if you agree to each of the points (depending on your preference). If you complete the consent online then you can download a copy to keep, or the researchers can print a copy to post to you using recorded delivery. If you provide verbal consent then the researcher will post a copy of the completed form to you using recorded delivery.
- We will record information about you, such as your age, sex, and ethnicity, as well as details of your stroke and your current medications. We can do this over the phone or you can fill in an online questionnaire to provide these details.
- We will ask you to wear a sleep monitor to assess your sleep. The monitor is like a wrist-watch that you wear on your unaffected arm for 7 nights. The monitor is waterproof, so you can wear it when showering or bathing.

Sleep monitor

- We will also ask you to fill in a sleep diary to tell us approximately what time you try to sleep each night and get up each morning. We will post these to you, or deliver them to your home, depending on your preference.
- We will ask you to complete questionnaires about your sleep, mood and feelings of fatigue. These can be done online or we can send you a paper copy. The questionnaires should take 10-20 minutes to complete in total.

1st Morning:

Day _____

I tried to sleep last night at: _____

I woke up this morning at: _____

Sleep diary

- We will arrange a date that suits you to perform a movement learning activity. We will deliver equipment to you at home, or we will post it to you (depending on your preference). The movement learning activity will require you to either squeeze a device in your hand, move a

joystick, or press buttons in a repeating sequence with your affected hand. The researchers will give you all the instructions you need to do this activity.

- We will ask you to practice the movement learning activity in the evening of one day (between 8-10 pm or shortly before you go to sleep) and then again the next morning (between 8-10am or at least 30 minutes after you wake up). The training/practice session in the evening will take less than 1 hour. The retest in the morning will take less than 30 minutes.
- After you have finished we will either collect everything from you or arrange to post it back (depending on your preference).

Example of movement tasks

Step 2

- Once we have received the questionnaire answers, sleep monitor and movement learning equipment back from you we will randomise you to either Group 1 or Group 2 and let you know which group you have been assigned to. One out of every three participants will be assigned to Group 1, and the remainder will be assigned to Group 2.

GROUP 1

- If you are in Group 1, we will not make any changes to the care you are receiving. You should continue all your normal treatments for the next 10 weeks.

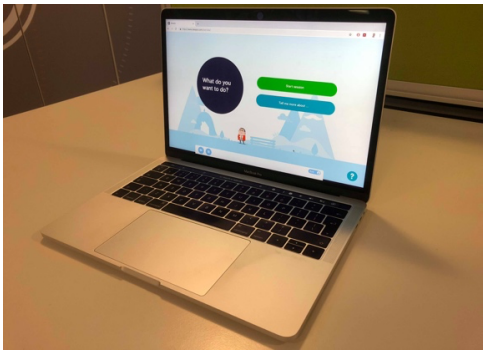
GROUP 2

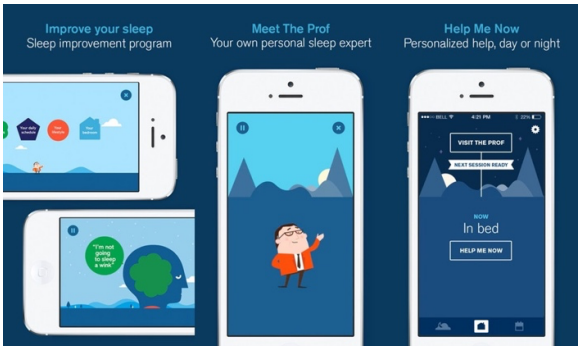
- If you are in Group 2, in addition to your usual care/treatments, you will be given access to Sleepio. Sleepio is an online cognitive behavioural therapy for insomnia programme. This programme is available as a website or iPhone app. Researchers will be able to provide assistance in setting up and using the programme where needed and will also provide you with a booklet of additional information that we think could be useful based on feedback we have received from other stroke survivors.
- Sleepio is designed to improve sleep through a number of different methods. Each day for the whole programme (up to 10 weeks) you will need to fill in a sleep diary online, giving

information about aspects of your sleep such as the times you went to bed and got up in the morning, how long you think it took you to fall asleep and whether you feel you woke up during the night. This should take approximately 5 minutes each day.

- The Sleepio programme includes weekly interactive sessions with a virtual professor lasting between 15-20 minutes each. These sessions will give you advice on how to make some changes to improve your sleep quality. This programme has been shown to be effective at improving sleep quality in people with sleep problems. We are trying to understand if/how it may be useful as part of rehabilitation after stroke.

The reason we need two groups is that we need to understand how sleep and movement learning changes with usual stroke recovery as well as with the Sleepio programme





Example of Sleepio programme

Step 3

- After approximately 10 weeks, we will repeat the assessments from Step 1. This includes the questionnaires about sleep, mood and fatigue (online or paper copy), wearing the sleep monitor for 7 nights, filling in the sleep diary and performing the movement learning task. We will also ask some questions about the 10-week study period (online or paper copy).
- As with Step 1, we can post or deliver the equipment to your home, depending on your preference.
- After you have finished, we will either collect everything from you or arrange for you to post it back (depending on your preference). This will be the end of the main part of the study. If you were in Group 1, you will be given free access to the Sleepio programme if you would like it.

Step 4: Optional

- You will be offered 4 weeks of home-based training for your affected hand/arm. This is available regardless of which Group you were allocated to (Group 1 or Group 2).

- If you would like to take part in this aspect of the study, we will first come to your home to assess how much you can currently move your affected side, using standard clinical assessments. These will require you to make everyday movements with your hand and arm. The researcher will explain these in detail and demonstrate what you need to do. These assessments should take less than 1 hour.
- You will then be given a device called Gripable, to use for 4 weeks. The Gripable contains various games to train different types of hand movements which may help you to use your arm more in everyday life. The device is connected to a tablet, which will be provided to you.

Gripable device

- We will ask you to try to use the Gripable device for 1 hour per day. It is up to you if you do this all at once or over several short sessions spread over the day.
- Since this is quite a new form of treatment, we would like to understand whether people are able to use it regularly and find it useful. To do this we would like you to complete a diary detailing how often, and for how long, you use it each day. Please be honest.
- At the end of the 4 weeks, we will come to your home again to repeat the clinical assessments, and collect the Gripable device from you. We will ask for your feedback on how you found it to use the device.

Date _____

Please indicate how many sessions you did today

I did not use the device today	
Once	
Twice	
Three times	
More than Three times	

Estimated total time spent (add all the sessions today up)

Less than 10 minutes	
10-30 minutes	
30-60 minutes	
More than 1 hour	

Comments:

Example of Gripable training diary

What should I consider?

Not everyone can take part in this research.

You will be unable to take part if you do not have enough movement of your affected side to perform the movement learning task. You may be unable to take part if you do not have reliable access to the internet or are unable to use an internet-based programme.

You may be unable to take part if you:

- have another neurological (brain) condition, other than stroke,
- have a diagnosed sleep disorder (such as sleep apnea),
- have uncontrolled seizures (fits),
- have a planned hospital or rehabilitation admission in the next 4 months that would affect your ability to do the tasks required of the study.
- have had previous psychological therapy for insomnia (in the past 12 months)
- are currently pregnant

Please ask the researcher if you are unsure.

If we are to visit you in your home then before we come we will provide you with additional information about the precautions we are taking for safety in relation to the Coronavirus (COVID-19) pandemic. All equipment is thoroughly cleaned before and after use.

What are the possible benefits of taking part?

We hope that you will find the experience interesting and enjoyable. You may experience an improvement in your sleep quality if you use the Sleepio programme. You may experience an improvement in the movement of your hand/arm if you undergo the optional training component.

We hope that the results of the study will help us to improve sleep for other stroke survivors in the future. We also hope to better understand the role of sleep in recovery after stroke, and that this will in the future lead to the development of new treatments to improve rehabilitation outcomes.

Are there any possible disadvantages or risks from taking part?

- Some people with sensitive skin experience a mild skin irritation when wearing the sleep monitor on their wrist. This should go away on its own, but you are free to remove the monitor during the day (or entirely) if you wish. You can continue in the study even if you are unable to wear the sleep monitor for the full time.

- Occasionally people find it upsetting to complete questionnaires asking about sleep and mood. You are free to take a break or stop at any time if you do not wish to continue. You can continue in the study even if you do not complete the questionnaires. These questionnaires are for the research, and are not for diagnostic purposes. If you feel that you are distressed or low in mood then it is recommended that you contact someone to speak to, such as your General Practitioner (GP).
- Part of the Sleepio programme involves a technique called 'sleep restriction' where you spend less time in bed than normal to try to improve your sleep pattern. Some people experience tiredness initially following reduced sleep as part of this adjustment to your sleep schedule. This part of the Sleepio programme is thought to aid your sleep overall. In order to reduce any potential risks, we advise you to avoid driving or operating dangerous machinery if you are excessively tired. You will be provided with additional guidance for how to manage excessive daytime tiredness and you are free to contact the researchers at any point if you are concerned.
- It is possible you will be assigned to Group 1, which does not include testing of the Sleepio programme. If so, you will be given free access to the Sleepio programme after you finish in the study if you would like it. Group 2 participants will also be able to continue to access the Sleepio programme after finishing the study.

Will my General Practitioner/family doctor (GP) be informed of my participation?

If you would like us to, we will send your GP a letter to let them know that you are taking part in the study.

One of the questionnaires that asks about your sleep may indicate that you are at risk of a sleep-related breathing disorder. We are using this for research only, and not for diagnostic purposes. As such, should this occur, we will provide you with a letter to take to your GP for further consideration.

Will I be reimbursed for taking part?

- There are no anticipated expenses for you to take part in the study. You will receive £50 as a thank you for your time upon completion of the study.
- Access to the Sleepio programme and the Gripable device will be provided free of charge.
- If you are posting paperwork or equipment to us then we will provide prepaid parcels or arrange couriers for you, so you will not be "out of pocket".

Will my taking part in the study be kept confidential?

- Yes. We will assign you a unique code which will be used to collect all study data, rather than using your name.
- Responsible members of the University of Oxford, or the NHS trusts may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

What will happen to my data?

- UK Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest.' The University of Oxford, based in the United Kingdom is the data controller and is responsible for looking after your information and using it properly.
- We will be using information from you in order to undertake this study and will use the minimum personally-identifiable information possible. We will keep identifiable information about you (name, home address, contact details) until the results of the study have been published and we have sent you a summary of the results.
- This excludes research documents with personal information, such as consent forms, which will be held securely at the University of Oxford for 5 years after the end of the study. Identifiable data, such as your name, address, email address will be stored securely using University servers.
- Consent forms will be stored electronically or in paper form at the Wellcome Centre for Integrative Neuroimaging, University of Oxford.
- Data collected by Sleepio (Big Health Ltd) will be stored (unless you request deletion) indefinitely in a secure database. Personally identifiable information collected from Sleepio will be transferred, uploaded and stored securely in Big Health data centres, hosted by AWS (Amazon) in the United States. This data includes your name, email address, study ID code and health information. All data is stored fully encrypted and complies with UK and European General Data Protection regulations. Upon signing up to Sleepio, you will need to agree to the privacy policy (https://www.sleepio.com/privacy/) and terms and conditions (https://www.sleepio.com/terms) which state that Big Health will act as Data Controller for these data and therefore will retain access to said data beyond the duration of the research

study. Should you want your data to be deleted you can submit a request to Big Health's Security, Privacy and Compliance Officer, as outlined in the privacy policy.

- The researchers will have access to information that you enter into the Sleepio programme, including your participant ID code, time joined, date of last login and current session status, sleep scores (from sleep diary inputs) and your case file which shows your Sleepio "to do" list and changes in sleep efficiency. Data sent from Sleepio to the researchers will be encrypted (password protected).
- If you choose to take part in the optional hand/arm training component, you may need to make an account with Gripable Ltd. This will include entering your email address or phone number, the condition you have (i.e. stroke) and which hand you are training (right or left). Data collected by the device, such as the time spent training, number of repetitions and movement scores are stored on the Gripable Ltd server held within the UK. Researchers involved in the study will have access to this data. For further information, visit: https://gripable.co/privacy-policy and https://gripable.co/terms-conditions
- If you lose capacity to consent to the study (i.e. you are no longer able to make decisions for yourself about being involved in the project) then we would still use any data collected from you up until that time.
- To provide the payment for your participation we will pass your contact information (name, address, email address), bank details and nationality to the University of Oxford finance department to arrange the payment. This is necessary for us to fulfil our obligations to you as part of your agreement to participate. If you do not want to provide this information for this purpose then you can be given a shopping voucher (e.g. Amazon) instead.
- Research data may be transferred to, and stored at, a destination outside the UK and the European Economic Area to be used in other research studies. It will be in a form that does not identify individuals.
- If you agree to your details being held to be contacted regarding future research, we will retain a copy of your consent form until such time as your details are removed from our database but will keep the consent form and your details separate.
- UK Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at

https://compliance.web.ox.ac.uk/individual-rights

You can find out more about how we use your information by contacting Dr Melanie Fleming: sleep-win@ndcn.ox.ac.uk

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

Participation is voluntary and you are free to withdraw at any time, without giving a reason. Withdrawal will not affect the medical or rehabilitation care you receive.

If you decide to withdraw from the study, then any data collected from you up to that point may still be used for the study.

What will happen to the results of this study?

- The findings from the research may be written up in a clinical scientific publication, as a lay summary on our website, and presented at conferences and stroke support group meetings. It will not be possible to identify you from any report or publication placed in the public domain.
- We will provide you with a lay summary of the results after the study results have been published. We may also provide you with a summary of your personal results if you would like us to.
- Some of the research being undertaken may also contribute to the fulfilment of an educational requirement (e.g. a student thesis).
- Research data may be transferred to, and stored at, a destination outside the UK and the European Economic Area to be used in other research studies. It will be in a form that does not identify individuals.

What if there is a problem?

- The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study. NHS indemnity operates in respect of the clinical treatment which is provided.
- If you wish to complain about any aspect of the way in which you have been approached or treated, or how your information is handled during the course of this study, you should contact Dr Melanie Fleming, Chief Investigator; email melanie.fleming@ndcn.ox.ac.uk or phone 01865 611 461, or you may contact the University of Oxford Research Governance, Ethics and Assurance (RGEA) office on 01865 616480, or the director of RGEA, email rgea.complaints@admin.ox.ac.uk.
- The Patient Advisory Liaison Service (PALS) is a confidential NHS service that can provide you with support for any complaints or queries you may have regarding the care you receive as an

NHS patient. PALS is unable to provide information about this research study. If you wish to contact the PALS team please contact: < add phone and email address >.

How have patients and the public been involved in this study?

Stroke survivors helped develop the research topic and what research questions we are asking. Stroke survivors were involved in reviewing the Participant Information Sheet.

Who is organising and funding the study?

The study is being organised and is sponsored by the University of Oxford.

The study is funded by Guarantors of Brain and the Wellcome Trust, and supported by the NIHR Oxford Biomedical Research Centre.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given favourable opinion by Leicester Central Research Ethics Committee.

Participation in future research:

If you agree to be contacted about future research studies then your contact details will be held securely, accessed through encrypted and password protected University laptops. Agreeing to be contacted does not oblige you to take part in future research. You can be removed from this register at any time you wish.

Further information and contact details:

Please contact Dr Melanie Fleming

OR

Barbara Robinson

Email: sleep-win@ndcn.ox.ac.uk

Phone: 01865 611 461 OR 07864800761

Wellcome Centre for Integrative Neuroimaging

John Radcliffe Hospital, Oxford OX3 9DU

Thank you for reading this information.