Department of Medicine
University of Otago, Wellington
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Phone number: 020 4160 4900

Participant Information Sheet - Therapist

Study title: Experiences of the use of an iPad application (ADOC-E) for shared decision making around goal setting in rehabilitation: a qualitative descriptive study

Locality: ABI Rehabilitation in Porirua, Hutt Valley DHB and Auckland DHB

Ethics committee: Northern B HDEC ref n. 20/NTB/40

Sponsor: University of Otago, Wellington

Lead investigator: Carla Strubbia, PhD candidate, Department of Medicine, University of Otago

Contact phone number: 020 4160 4900

You are invited to take part in a study on the experience of the use of an iPad application called ADOC-E for shared decision making around goal setting in rehabilitation. Whether or not you take part is your choice. If you don't want to take part, you don't have to give a reason, and it won't affect the care you receive. If you do want to take part now, but change your mind later, you can pull out of the study at any time. This study is being conducted as part of a PhD by the University of Otago, Wellington campus.

This Participant Information Sheet will help you decide if you'd like to take part. It sets out why we are doing the study, what your participation would involve, what the benefits and risks to you might be, and what would happen after the study ends. We will go through this information with you and answer any questions you may have. You do not have to decide today whether or not you will participate in this study. Before you decide you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers. Feel free to do this.

If you agree to take part in this study, you will be asked to sign the Consent Form. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep.

This document is 6 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

WHAT IS THE PURPOSE OF THE STUDY?

We have made an English-language version of a Japanese iPad app called the "Aid for Decision-making in Occupation Choice" (ADOC). We made ADOC-E to help health professionals talk to patients about their goals and what they want from therapy. This will help patients participate more in decisions about the direction of their rehabilitation, making therapy more meaningful for them.

In this study, we want to examine the impact of ADOC-E on the rehabilitation process, patient and therapist experiences, and on patient health outcomes.

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This study has been approved by the Northern B Health and Disability Ethics Committees (HDECs), ref number xx, on the xx/xx/xx.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

You can participate in this study if:

- You are qualified and registered physiotherapist, occupational therapist, speech therapist or nurse.
- You are usually involved in goal setting with patients.

We wish to recruit 6 to 12 allied health professionals to this study. We also will be recruiting 6 to 12 patients to participate in this study. We will ask you to give to the patient that you have identified as potential participant to the study the Participant Information Sheet. After, we will then meet the patient and explain what the study consist, answer related questions and we will also be responsible for the sign of the consent form.

We would like you to use ADOC-E with your patient to discuss goals for the therapy. You do not need any experience with computers or iPads. You will be provided with an iPad, with the ADOC-E app and with a short training in the use of the app. ADOC-E uses pictures of people doing activity of everyday living, including personal care activity, physical activities, work activities and leisure activities. There are a total of 94 illustrations matched with text, which briefly explain the intended activity. We want to ask you to choose a maximum of 20 activities that you consider important to set as goal for your patient. After, you will discuss together with your patient to choose up to 5 urgent and most meaningful activities to focus on rehabilitation.

After that, we want to meet you to ask you few questions about your views on ADOC-E: how useful you found it; what you liked or didn't like about it; how did it influence the goal setting process. We want to audio-record our discussion with you so we can make sure we do not miss anything important that you say. We want to interview you in two occasions, the first time shortly after using ADOC-E and the second time at approximately 4 weeks later. This meetings may take up 30-60 minutes. We will meet you inside the rehabilitation facility during working hours in a designated, quiet and safe room where you will feel at ease. We can stop and start your involvement in the study, even meet with you on different days, to fit in with your working schedule. Remember that you can decide to leave the study at any time you choose.

We will be interested in your views on ways we could make the app better. We will use this information and any other comments you make, to understand whether ADOC-E should be part of the clinical practice or not. We will also send the information to the developer of the app that he will use to improve ADOC-E, which will make the application more useful in therapy in the future.

We would like to also collect a little bit of information about you, so we can say what types of people participated in our study. This will included information about your gender, age and profession.

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HOW LONG WILL THE STUDY RUN FOR?

The study will run from March-April 2020 to September 2020.

WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?

We are not aware of any risk to you as a result of your participation in this study.

WHO PAYS FOR THE STUDY?

This is not a funded study. The study does not cost any money. The researchers involved in the study are working on it as part of their work. To thank you for your time and involvement, we will donate you the last version of ADOC-E. The rehabilitation service will receive on loan an iPad to use for the all duration of the study, plus they will receive as gift the last version of ADOC-E.

You will receive a free version of ADOC-E to thank you for your important contribution.

WHAT IF SOMETHING GOES WRONG?

If you were injured in this study, you would be eligible to apply for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.

If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won't affect your cover.

WHAT ARE MY RIGHTS?

It is important you to know that you are welcome to withdraw from the study at any stage, without needing to say why and without this affecting your medical care. Your involvement or non-involvement in this study has no impact on your work neither now nor in the future. We will not collect any information that could be used to identify you personally.

We will keep your name and contact details separately from the study data. We will only use your name and contact details to report back to you on the outcomes from the study, if you wish so.

All study data will be anonymous and your personal information will be kept confidential. When reporting on the completed research, we will not identify any individual people either directly or indirectly. Only the researchers involved in this study will be access to the raw study data.
We keep all of our data on a password protected computer during the study.

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WHAT HAPPENS AFTER THE STUDY OR IF I CHANGE MY MIND?

After the study, we destroy all the audio-recordings of the data and just keep the written study data (which will be anonymous data) locked in a filing cabinet in a private University office room. We are required to keep this study data for 10 years before destroying it.

If you wish, within ten months from the end of the study, we will send you by post mail or e-mail a summary of the results from the study.

WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?

If you have any questions, concerns or complaints about the study at any stage, you can contact:

Name, position: Carla Strubbia, PhD candidate, University of Otago
Telephone number: 020 4160 4900
Email: carla.strubbia@postgrad.otago.ac.nz

Name, position: William Levack, Dean and Professor, University of Otago
Telephone number: 04 918 6279
Email: william.levack@otago.ac.nz

Name, position: Rebecca Grainger, Associate Professor, University of Otago
Telephone number: 04 385 6783
Email: rebecca.grainger@otago.ac.nz

If you want to talk to someone who isn't involved with the study, you can contact an independent health and disability advocate on:

Phone:	0800 555 050
Fax:	0800 2 SUPPORT (0800 2787 7678)
Email:	advocacy@advocacy.org.nz
Website:	https://www.advocacy.org.nz/

For Maori Heath support contact:

Name, position: Bernadette Jones, Research fellow, University of Otago
Telephone number: 04 918 6845
Email: bernadette.jones@otago.ac.nz

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

Phone:	0800 4 ETHICS
Email:	hdecs@moh.govt.nz

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Ethics committee ref.:

Sponsor: name and location

Lead investigator: Carla Strubbia, PhD candidate, Department of Medicine, University of Otago

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Please tick to indicate you consent to the following:

I have read and understood the Participant Information Sheet.	Yes ☐ No ☐
I have been given sufficient time to think about whether or not to participate in this study.	Yes ☐ No ☐
I have had the opportunity to talk with my Doctor, whanau/family, friend or other people of my choice to help me ask any questions and understand the study.	Yes ☐ No ☐
I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet.	Yes ☐ No ☐
I consent to the research staff collecting and processing my information.	Yes ☐ No ☐
I know that my participation in the study is entirely voluntary (my choice), and that I am free to withdraw from the study at any time without having to give a reason and without this affecting my work.	Yes ☐ No ☐
I understand that my participation in this study is confidential and that no material, which could identify me personally, will appear in any spoken or written report of the study at any stage.	Yes ☐ No ☐

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I understand the nature and size of the risks of discomfort or harm which are explained in the Information sheet.	Yes ☐ No ☐
I know that all personal identifying information will be removed from the paper records and electronic files, and that these will be stored in a locked room on a University secure storage, and kept for at least ten years.	Yes ☐ No ☐
I understand I will be given the last version of the app ADOC-E.	Yes ☐ No ☐
I know who to contact if I have any questions about the study in general.	Yes ☐ No ☐
I understand my responsibilities as a study participant.	Yes ☐ No ☐
I wish to receive a summary of the results from the study.	Yes ☐ No ☐

Declaration by participant:

I hereby agree to participate in the study.

Participant's name: _____

Signature: _____ Date: _____

Declaration by member of research team:

I have given a verbal explanation of the research project to the participant, and have answered the participant's questions about it.
I have explained the study and believe the participant understand the study and has given informed consent to participate.

Researcher's name: _____

Signature: _____ Date: _____