Health:SALHN Office for Research
To: Ying Yu
Cc: Lily Xiao; Claudia Meyer <cmeyer@boltonclarke.com.au>; Tan, Kai Ping (Health) <KaiPing.Tan@act.gov.au>; Chen, Langduo (Health) <Langduo.Chen@sa.gov.au>; Chapman, Michael (Health) <michael.chapman@act.gov.au>

Fri 14/10/2022 1:28 PM

Dear Ying Yu,

OFR reference: 230.21
Title: Creating partnerships in iSupport program to optimise carers impact on dementia care
Principal investigator: Professor Lily Xiao

The amendment to the above study has been reviewed and approved by the SAC HREC.

Approval period: 11 January 2022 – 11 January 2025

The following documents have been reviewed and approved:

Document	Version	Date
Project amendment form	-	10 August 2022
Protocol	1.08	9 August 2022
Carer PICF	1.08	4 August 2022
iSupport flyer	1.08	10 August 2022

The terms and conditions of ethics and governance approval remain unchanged from the original approval. Please note a formal approval letter will not be provided. Please retain a copy of this email as evidence of approval.

Please note that the SAC HREC strongly encourages all investigators to obtain Good Clinical Practice (GCP) training. A free training resource is available from the SALHN Office for Research webpage here.

Kind Regards,

Dominic How

On behalf of

Professor Bill Heddle
Chair
SAC HREC

Project Amendment Form

Researchers are required to complete and submit this form to the Office for Research outlining project amendments for ethics approval and governance acknowledgement

Complete this form to notify the Office for Research of the details of the amendment. Please refer to the National Statement on Ethical Conduct in Human Research, Sections 3.3.22 and 5.5 for advice on project amendments.

Instructions

Researchers are required to provide written details of project amendments to the SALHN Office for Research. The amendment notification process is a requirement of continuing ethics approval and institutional authorisation and aims to eliminate immediate risks to participants or to assist in the viability of recruitment or other research administration.

Please complete this form in conjunction with the Check list on page 4 then email completed form and updated documents to: Health.SALHNOfficeforResearch@sa.gov.au

Please do not submit this amendment if the Site Specific Assessment form is under review or has not been authorised.

Date: 4/8/2022
Office for Research reference number: 2021/HRE00288
Application type: ☐ **Single site (SALHN only) – requires both ethics and governance review** ☒ **Multi-site (SALHN Lead) requires both ethics and governance review** ☐ **Multi-site (SALHN non-lead) – requires governance review only**
Project Title: Partnership in iSupport program' to optimise carers' impact on dementia care: A randomised controlled trial
Principal Investigator: Prof. Lily Xiao

Have there been previous amendments to this project?

☒ **Yes - Please provide a summary of amendments** We made the following amendments: 1) Using Zoom software instead of Cliniko for group meetings; 2) we would like to request a waiver of consent to pre-screen (apply for an exemption of patient consent to access their personal information for research purposes. 3) We add the Global Deterioration Stage between normal ageing and Alzheimer's disease (GDS) or The Rowland Universal Dementia Assessment Scale (RUDAS) in addition to Mini-Mental State Examination (MMSE) for researchers to choose to assess the dementia stages for carer recipients in order to know their eligibility to participate in the study. 4) Extend participants' recruitment to the community using the following method: a) contact the local council to distribute recruitment flyers to their support/activity groups (i.e., but not limited to Mitcham council, Onkaparinga council); b) Put up flyers on social media (i.e., Facebook and Twitter); c) put up flyers on the notice board in the community; **d**) distribute flyers to local church group;e) distribute flyer to super GP clinic 5) participant's inclusion criteria: if a care recipient has no formal dementia diagnosis but meet the following three criteria will be included: a) cognitive deterioration on a valid measure (e.g., MMSE, GDS or RUDAS); b) change in the person's ability to self-care (on Blessed dementia dependence score, Appendix I) and c) change in behaviour or personality (on Blessed dementia dependence score, Appendix I). Details of the assessment are introduced in Appendix I Care recipient assessment instruction for research assistant. 6) update our participant's withdrawal consent form for MBS/PBS

data extraction according to Service Australia's approval. 7) We would like to record messages between participants' and program facilitator.8) Dr Shahid Ullah who does not involve in participants recruitment will randomly assign participants (deidentified) into the intervention group and usual care group instead of using a third party.

☒ **No**

Approval / Authorisation

Does this project have SAC HREC approval?

☒ **Yes - when does your SAC HREC approval expire? 11 Jan 2025**

☐ **No – when did your SAC HREC approval expire? Click here to enter text.**

Does this project have governance authorisation?

☒ **Yes - please provide the authorisation date: Click here to enter text.**

☐ **No**

☐ **Pending**

Amendment details

It is important to provide a detailed description on what is changing and why it is changing to assist the committee with the review of this amendment.

Clinical drug trials

For investigator Brochure and/or protocol amendments, please do not copy and paste the summary of changes into this document. The researchers should clearly explain the nature of the changes in lay terms.

Please provide detailed summary of the amendment: We would like to make the following amendment: 1) updated participants' inclusion criteria to include all people living with dementia instead of only moderate and mild dementia; we also removed the requirement of having access to the internet, smartphone or computer to include more carers; 2) After we screen the historical data (we have an approved waiver of consent for pre-screening), we will email, text, phone or post our research information to potential participants.

Please provide a reason for the changes 1) 1) We experienced extreme difficulty in recruitment, especially with recent covid case spikes in the hospital. We noted that the majority of carers of people living with dementia are at an old age and have no access to the internet or smartphone. We will offer a hardcopy handbook and phone calls to support this group of people. 2) Clinicians who are working in the ward or clinics are extremely busy and have no time to distribute our research information. We would like to email, text, phone or post our research information to potential participants after hospital employed facilitator screened historical data.

Participants

How many participants have been recruited to date? 13

Do these changes create new risks for the participants? ☐ Yes ☒ No

If yes please outline the new risks, such as changes to confidentiality, physical or psychological risk, and increased time commitments: Click here to enter text.

If the study is approved by the SAC HREC, please list all approved study sites this amendment applies to: Southern Adelaide Local Health Network, Resthaven SA, Canberra Health Services

Conflicts of interest

Are there are any new or existing conflicts of interest that need to be declared?

Please refer to Office for Research Conflicts of Interest information sheet on the definition of a conflict of interest and how it needs to be disclosed and managed.

☐ Yes – please provide details Click here to enter text.

☒ No

Investigator brochures and protocols

Have there been any changes to the IB for the following:

☐ Yes ☒ No - Has an explanatory statement been provided?

☒ *Yes ☐ No - Does the PICF need to be updated?

☒ *Yes ☐ No - Does the protocol need to be updated?

☐ *Yes ☒ No - Is there any change to the participant safety?

☐ Yes ☒ No - Serious Adverse Events

☐ Yes ☒ No - Disease interactions

☐ Yes ☒ No - Drug interactions

☐ Yes ☒ No - Efficacy of the treatment

If yes to any of the above, please ensure updated details /documents have been provided and the changes are outlined in the explanatory statement on how these changes affect SALHN trial participants.

Office for Research fees

Non-Clinical trials (studies without one or more health-related intervention) do not incur fees in accordance with the SA Health Research Ethics and Governance Fees Schedule. If you would like to request fees be waived or reduced for this study please fill in a Waiver of Fees application form and include this with your submission documents.

Review fees

Are fees applicable to this research (based on the SA Health Fee Schedule) ☐ Yes ☒ No

☐ Clinical trial with full sponsorship

☐ Cooperative Research Group

☐ Non commercially sponsored Clinical Trial

☐ Health and Medical Research

If your study is a clinical trial, are you requesting a reduction or waiver of ethics or governance fees?

☐ Yes / ☐ No.

DETAILS FOR INVOICING:

This submission to SALHN may incur review fees (clinical trials only, fee waiver can be requested), in accordance with the SA Health ethics and governance fee schedule. The details provided below will be invoiced to the sponsor and should indicate who to address the invoice to.

Please list invoice details below:

Sponsor/Institution Name:

Address 1

Suburb

Additional details to include in the invoice:

Please list all documents being submitted for the amendment.

The details that you provide below will be replicated in the HREC approval and governance acknowledgement letter.

Please ensure all documents have updated version numbers and dates in the footer.

The updated HREA only needs to be signed by the Coordinating Principal Investigator.

- Services Australia Participant Withdrawal of Consent Form Creating ‘partnerships in iSupport program’ to optimise carers’ impact on dementia care (Legal Representative)
- Services Australia Participant Withdrawal of Consent Form Creating ‘partnerships in iSupport program’ to optimise carers’ impact on dementia care
- Appendix C iSurpport study PICF_Carers_1.08
- iSupport study protocol_v1.08
- **iSupport study flyer_v1.08**
- **Declaration**

- I confirm the information provided in this form is true and correct.
- **Chief / Principal Investigator: Lily Xiao**
- **Date**: Click here to enter text.

- **Signature**: 

Checklist

SAC HREC is the lead committee

- Please ensure all fields in this form are filled out.
- If appropriate, update the application form with the amendment details, using track changes.
  - If the application form (i.e. LNR or HREA) is updated the listed investigators must re-sign the declarations on the last page of the application.
- Ensure your amended PICF (if required) is submitted with tracked changes and new version number and date in the footer.
- Please ensure all submitted documents have an updated version number and date in the footer.
- For multi-site applications, the master PICF is submitted to the SAC HREC and once approved, the site specific version (tracked and clean) to the RGO.
- Investigator brochures and protocols (for commercially sponsored trials)
  must be submitted with:
  - An explanatory statement in the lay summary of this form, drawing attention to significant issues arising from IBs and with specific comments as to their significance and measures that do or do not need to be taken (such as PICF changes and updates to the protocols).
  - A detailed summary of changes.
  - A version showing tracked changes provided either by the Sponsor or Principal Investigator.
  - Investigator brochures will not be accepted if they are password protected.
- Supply all other documents required to support the amendment.
- Sub study / extension study – prospective studies must be submitted as a new application and will not be accepted as an amendment.

For RGO review only

- Please ensure all fields in this form are filled out.
- Please provide a copy of the HREC approval letter for the amendment
- Ensure your amended PICF (if required) is submitted with tracked changes and new version number and date in the footer.
- Please ensure all submitted documents have an updated version number and date in the footer.
- For multi-site applications, the master PICF is submitted to the lead HREC and once approved, the site specific version (tracked and clean) to the RGO.
- Investigator brochures and protocols (for commercially sponsored trials)
  must be submitted with:
  - An explanatory statement in the lay summary of this form, drawing attention to significant issues arising from IBs and with specific comments as to their significance and measures that do or do not need to be taken (such as PICF changes and updates to the protocols).
  - A detailed summary of changes.
  - A version showing tracked changes provided either by the Sponsor or Principal Investigator.
  - Investigator brochures will not be accepted if they are password protected.
- Supply all other documents required to support the amendment.