DALHOUSIE UNIVERSITY

RESEARCH ETHICS BOARDS APPLICATION FORM

Prospective Research

This form should only be used if new data will be collected. For research involving only secondary use of existing information (such as health records, student records, survey data or biological materials), use the *REB Application Form – Secondary Use of Information for Research.*

This form should be completed using the *Guidance for Submitting an Application for Research Ethics Review* available on the Research Ethics website (application instructions).

SECTION 1. ADMINISTRATIVE INFORMATION [File No: office only]

Indicate the preferred Research Ethics Board to review this research:

[x] Health Sciences OR [ ] Social Sciences and Humanities

Project Title: **AI-Momentous - An Alzheimer's helper app**

1.1 Research team information				
Dalhousie researcher name	**Miles Redgate**			
Banner #	B00705540	Department	FACS	
Email (@dal)	miles.redgate@dal.ca	Phone	(782) 882-0740	
Study start date	10/11/2019	Study end date	10/30/2019	
Co-investigator names and affiliations	Aishwarya Narayanan, Sithara, Vishaali			
Contact person for this submission (if not lead researcher)	Name	Miles Redgate		
	Email	miles.redgate@dal.ca	Phone	(782) 882-0740

1.2 For student submissions:			
Degree program	Master/Bachelor of Applied Computer Science		
Supervisor name and department	Rita Orji – Faculty of Computer Science		
Supervisor Email (@dal)	Rita.Orji@dal.ca	Phone	NA

Department/unit ethics review (if applicable). **Postgraduate minimal risk research only**.
Attestation: [ ] I am responsible for the unit-level research ethics review of this project and it has been approved. Authorizing name: Sithara Date: 13th, Oct 2019

1.3 Other reviews: NA			
Other ethics reviews (if any)		Where NA	Status NA
Funding, if any (list on consent form)	Agency	NA	
	Award Number	NA	
Peer review (if any)	NA		

1.4 Attestation(s). The appropriate boxes *must* be checked for the submission to be accepted by the REB)
[x] I am the **lead researcher**. I agree to conduct this research following the principles of the Tri-Council Policy Statement *Ethical Conduct for Research Involving Humans* (TCPS) and consistent with the University *Policy on the Ethical Conduct of Research Involving Humans*. I have completed the TCPS Course on Research Ethics (CORE) online tutorial. [x] Yes [ ] No For Supervisors (of student / learner research projects): **[ ]** I am the **supervisor** for this research named in section 1.2. I have reviewed this submission, including the scholarly merit of the research, and believe it is sound and appropriate. I take responsibility for ensuring this research is conducted following the principles of the TCPS and University Policy. I have completed the TCPS Course on Research Ethics (CORE) online tutorial. [x] Yes [ ] No

SECTION 2. PROJECT DESCRIPTION

2.1 Lay summary

2.1.1 In lay language, describe the rationale, purpose, study population and methods. Include the background information or literature to contextualize the study. Mention what new knowledge is anticipated, and whether this is a pilot project or fully developed study. [500 words]

Alzheimer's is a disease associated with memory loss and a person suffering from this disease will find it very difficult to remember and accomplish simple tasks of day to day life. This disease has become one of the major problems all over the world. The patients have a tough time remembering simple tasks daily. Alzheimer's affects the patients on 7 different stages. Our app Al-momentous is intended for the patients who are affected up to stage 4(the beginning stages of Alzheimer's). As in, our application is meant to help people with early Alzheimer's disease navigate their day to day life easier, as well as provide doctors and health professionals with more data on a patient's day-to-day activities to help understand both how the disease is affecting them as well as if the patient's status is deteriorating.

The main objective of our study is to evaluate our app that helps users remember events, stay connected and engaged with friends and family and recognize faces of friends using face recognition technology. This app is intended to help users solve simple issues in their lives. Our team feels that this study is important as it could pave the way for helping out the patients whose memory is worsening over time. As there is no cure for this disease, we aim to improve their quality of life for as long as we can. Research suggests that stimulating one's memory and socializing especially by using a computer or a mobile app could slow down cognitive decline over time.

Background research based on the articles "Cultural Diversity and Alzheimer Disease: Introduction" [3] and "Alzheimer changes in nondemented patients younger than sixty-five: Possible early stages of Alzheimer's disease and senile dementia of Alzheimer type" [4] helped us identify the major difficulties faced by the patients and we considered this research as a base while building the foundation of low fidelity prototype.

The features of our app (Al-momentous) will include photos, events, contacts, helpline, Identify and remind me. Our prototype would be designed in such a way so that it addresses the common issues faced by Alzheimer's patients (stage 1-4). In this study we will also be detailing about the recruit plans and how we are envisioning to maintain the privacy of the users as well as how are we planning to mitigate the risks to keep the study safe and successful.

Since this study is done on a small scale with a limited number of participants, we would be considering this project as a pilot study. Further research can be continued by digging deeper into the real case scenarios with Alzheimer's patients. Our end goal of this particular milestone is to have a solid plan that helps us refine our prototype according to the results obtained from the user study.

2.1.2 If a phased review is being requested, describe why this is appropriate for this study, and which phase(s) are included for approval in this application.

[x] Not applicable

2.2 Research question

State the hypotheses, the research questions or research objectives.

Hypotheses:

By providing constant reminders and tracking the user's day to day activities, as well as support for minor struggles they might encounter, an app can help reduce the negative effects of Alzheimer's.

Research question:

1) Does using this kind of mobile app on a daily basis have a positive impact on people suffering from Alzheimers?

2) Will looking at pictures of the patient's acquaintances help them to remember their connection with them?

3) Does playing games that control stress and anger levels have a positive influence on patient's mental health?

2.3 Recruitment

2.3.1 Identify the study population. Describe how many participants are needed and how this was determined.

We hope to have around 5-10 participants for this study. Ideally, we would have people suffering from Alzheimer's to participate in the study. However due to the confines of this course, as well as the problems that naturally arise by studying people with memory loss problems, especially with such a low fidelity prototype that we would have. We will instead conduct the study during the lab session with the students who will be present during the lab session.

2.3.2 Describe recruitment plans and append recruitment instruments. Describe who will be doing the recruitment and what actions they will take, including any screening procedures. Describe and justify any inclusion / exclusion criteria.

As the study is supposed to be held during the lab session, the participants will be informed about the study through direct announcement about our study that is planned to be made during the lab session. Participants will then be given further instructions about the study procedures and have the option to drop out beforehand.

2.3.3 Describe any community or organizational permissions needed to recruit your participants (attach support letters). Describe any other community consent or support needed to conduct this research. (If the research involves Aboriginal participants, please complete section 2.10).

[ ] Not applicable

2.4 Informed consent process

2.4.1 Describe the informed consent process, including any plans for ongoing consent (how and when the research will be described to prospective participants, by whom, how the researcher will ensure prospective participants are fully informed). If non-written consent is proposed, describe the process. Address how any third-party consent (with or without assent) will be managed. Append copies of all consent/assent documents, including oral consent scripts.

Once the participants are selected for the study, they are given a written consent form (physical paper copy) with set of terms and conditions mentioned clearly explaining about the study and what kind of information will be used for the research process. Further, the research team will be fully involved in briefly describing about the consent forms and its details, which is planned to be explained during the one-on-one session with every participant to help them understand the process involved in the study. Once the participant is fine with all the terms and conditions mentioned in the consent form, they are required to provide their signature to confirm their approval in order to participate in the research study. Please see section 3.2 for our consent form.

2.5 Methods and analysis

2.5.1 Describe the study design, where the research will be conducted, what participants will be asked to do and the time commitment, what data will be recorded using what research instruments (append copies).

This study will take place in and during the lab for CSCI 6610. After informing users of the details of the study and obtaining their consent we will ask users to perform tasks relating to our low-fidelity prototype. We will collect quantitative and qualitative objective data on their performance during these tasks. Following the completion of all tasks we will perform a semi-structured interview with participants to gain insight that might help explain irregularities in the data collected earlier or to understand something that cannot be reflected in the data collected so far. After which the study is complete, and we will move on to data analysis. We expect the study to take approximately 10 minutes for each participant.

2.5.2 Describe plans for data analyses.

After the study we will aggregate the data from both the observation of the user using our prototype as well as the results from the interview. We will then examine the data for deviations from results or response we expected or hoped for. i.e. A task took 35 seconds complete when we expected to take 20 seconds.

2.5.3 Describe any compensation that will be given to participants and how this will be handled for participants who do not complete the study. Discuss any expenses participants are likely to incur and whether/how these will be reimbursed.

No compensation will be given for participants in this study, and we see no costs for participants either as it will take place during the course lab time.

2.5.4 Describe and justify any use of deception or nondisclosure and explain how participants will be debriefed.

[x] Not applicable

2.5.5 Describe the role and duties of local researchers (including students and supervisors) in relation to the overall study. Identify any special qualifications represented on the team relevant to the proposed study (e.g. professional or clinical expertise, research methods, experience with the study population, statistics expertise, etc.)

- Miles will be responsible for conducting the study and interviews.
- Aishwarya will be responsible for taking notes of qualitative data during the study.
- Sithara will be responsible for facilitating the low-fidelity prototype (changing images, providing text, etc.)
- Vishaali will be responsible for recording quantitative data during the study.
- There are no notable qualifications on the team in regard to this study.

2.6 Privacy & confidentiality

2.6.1 Describe any provisions for ensuring privacy and confidentiality (or anonymity). Describe who will have access to data and why, how data will be stored and handled in a secure manner, how long data will be retained and where. Discuss any plans for data destruction and/or de-identification.

The data gathered from the survey will not be disclosed to anyone other than the team involved in developing the prototype. The data will be stored on a team members computer and a backup will be maintained in the cloud. Appropriate access rights will be implemented in both the cloud and computer where the data is stored. The data will be maintained until the end of the course and would be destroyed at this time.

2.6.2 Describe how participant confidentiality will be protected when research results are shared. Discuss whether participants will be identified (by name or indirectly). If participants will be quoted address consent for this, including whether quotes will be identifiable or attributed.

The participant's identity will not be revealed in any form or response. The research team will ensure to maintain data confidentiality right from the beginning of the interview process. Once the research is complete, the data collected will be revealed in a generalized form (age groups, gender).

2.6.3 Address any limits on confidentiality, such as a duty to disclose abuse or neglect of a child or adult in need of protection, and how these will be handled. Detail any such limits in consent documents.

[x] Not applicable

2.6.4 Will any information that may reasonably be expected to identify an individual (alone or in combination with other available information) be accessible outside Canada? This includes sharing information with team members, collecting data outside Canada, use of survey companies, use of software.

[x] No

[ ] Yes. If yes, describe how you comply with the University *Policy for the Protection of Personal Information from Access Outside Canada*, such as securing participant consent and/or securing approval from the Vice President Research.

2.7 Provision of results to participants

2.7.1 The TCPS encourages researchers to share study results with participants in appropriate formats. If you plan to share study results with participants, discuss the process and format.

[x] Not applicable

2.7.2 If applicable, describe how participants will be informed of any incidental findings – unanticipated results (of screening or data collection) that have implications for participant welfare (health, psychological or social).

[x] Not applicable

2.8 Risk & benefit analysis

2.8.1 Discuss what risks or discomforts are anticipated for participants, how likely risks are and how risks will be mitigated. Address any particular ethical vulnerability of your study population. If applicable, address third party or community risk. Risks to privacy from use of identifying information should be addressed.

Alzheimer's is a very sensitive topic and the proper measure has to be taken evaluating the study in order to be successful. Since the participants have been selected from the class, they might feel that the condition is irrelevant to them when certain questions are being asked. This might put them in an uncomfortable situation while answering sensitive questions. Another risk is that a participant might get emotionally distressed while answering the questions if they know someone suffering from Alzheimer's. Also, if the participants are answering personal questions, they might have a fear of their data being compromised.

Risk Mitigation:

The research team will build a proper rapport with the participant before interviewing them. This puts the participant in a comfortable position while answering the questions. Participants are of course welcome to drop out at any time if the question cause too much discomfort to them

As mentioned under the section (Privacy and confidentiality), we will ensure to take various precautions to ensure the privacy of our and our participants data.

2.8.2 Identify any direct benefits of participation to participants (other than compensation), and any indirect benefits of the study (e.g. contribution to new knowledge)

Participants would always benefit when they take part research. It gives them an insight into how the research is being conducted and what kind of questions to expect. If the participant is a research student, the students will now be familiar with the interview process and all those questionnaires' will also get to know how to interview the participants when they are involved in a research study. As the research is based on the Alzheimer's app, they will gain knowledge about the disease. In the future, it might also help them identify early symptoms of Alzheimer's if their friends or loved ones are affected.

2.9 Conflict of interest

Describe whether any dual role or conflict of interest exists for any member of the research team in relation to potential study participants (e.g. TA, fellow student, teaching or clinical relationship), and/or study sponsors, and how this will be handled.

All participants are fellow students. However, we see no way to avoid this as it affects all members of our team. Though we see little risk of the implications of this conflict

[x] Not applicable

2.10 Research with Aboriginal peoples

[x] Not applicable

2.10.1 If the proposed research involves Aboriginal peoples, describe the plan for community engagement (per TCPS Articles 9.1 and 9.2). Attach supporting letters, research agreements and other relevant documents, if available. If community engagement is not sought, explain why the research does not require it, referencing article 9.2.

2.10.2 State whether ethical approval has been or will be sought from Mi'kmaw Ethics Watch or other Indigenous ethics review group(s), and if not, why the research does not fall under their purview.

2.10.3 Describe any plans for returning results to the community and any intellectual property rights agreements negotiated with the community, with regard to data ownership. If there are specific risks to the community involved, ensure these have been addressed in section 2.8.1.

***2.11** Clinical trials*

[x] Not applicable

2.11.1 Does the proposed research require clinical trial registration, in keeping with national and international regulations?

[ ] No. Please explain why not.

[ ] Yes. Please indicate where it was registered and provide the registration number.

2.11.2 If a novel intervention or treatment is being examined, describe standard treatment or intervention, to indicate a situation of clinical equipoise exists (TCPS Chapter 11). If placebo is used with a control group rather than standard treatment, please justify.

2.11.3 Clearly identify the known effects of any product or device under investigation, approved uses, safety information and possible contraindications. Indicate how the proposed study use differs from approved uses.

2.11.4 Discuss any plans for blinding/randomization.

2.11.5 What plans are in place for safety monitoring and reporting of new information to participants, the REB, other team members, sponsors, and the clinical trial registry? These should address plans for removing participants for safety reasons, and early stopping/unblinding/amendment of the trial. What risks may arise for participants through early trial closure, and how will these be addressed? Are there any options for continued access to interventions shown to be beneficial?

***2.12** Use of personal health information*

[x] Not applicable

2.12.1 Describe the personal health information required and the information sources and explain why the research cannot reasonably be accomplished without the use of that information. Describe how the personal health information will be used, and in the most de-identified form possible.

2.12.2 Will personal health information be combined with information from other sources to form a composite record (data linkage)? Will the research create individually identifying health information by combining information from two or more databases without the consent of the individuals who are the subjects of the information (data matching)? *[ ] No.* *[ ] Yes. Describe the other information and how linkage will be conducted, and/or why data matching is required.*
2.12.3 Describe reasonably foreseeable risks to privacy and how these will be mitigated.

SECTION 3. APPENDICES

Appendix A. Interview Questions

1) On a scale of 1-5 (1 being very difficult and 5 being very easy), how difficult was it to accomplish the tasks given in this study?
2) Where there any tasks that stood out as more difficult than the rest? Easier?
3) Is there anything about this app that you would change design wise?
4) What about features that would benefit the app or current features that hinder it?
5) On a scale of 1-5 (1 being not at all useful and 5 being very useful), how useful do you think our app would be for helping those with Alzheimer's?
6) Other thoughts?

Appendix B. Low fidelity Prototypes

Figure 1 - Mockup of the App home screen

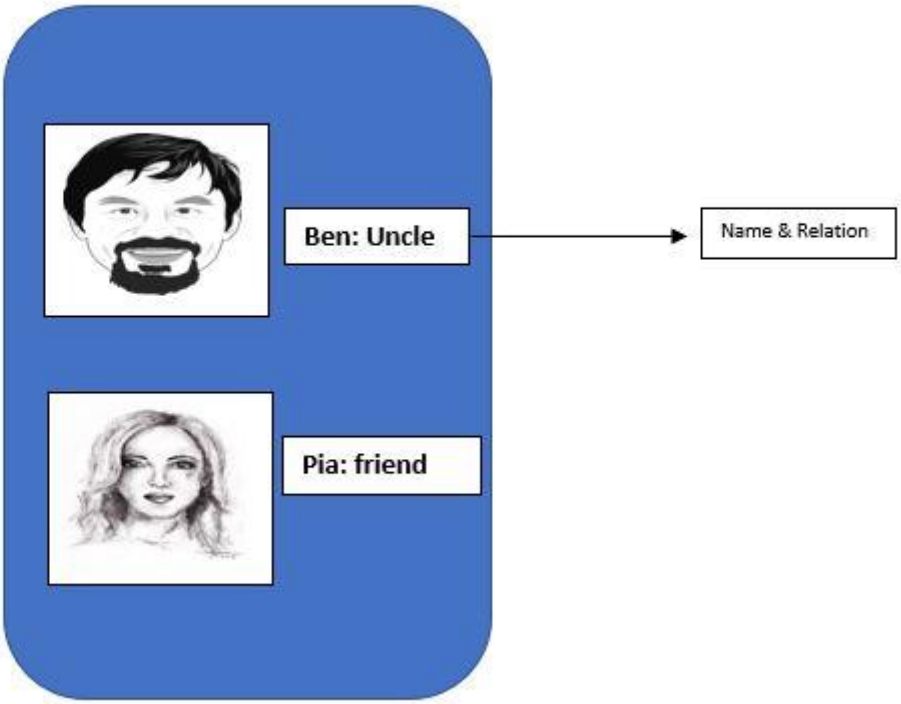

Figure 2 - Mockup screen of photo screen

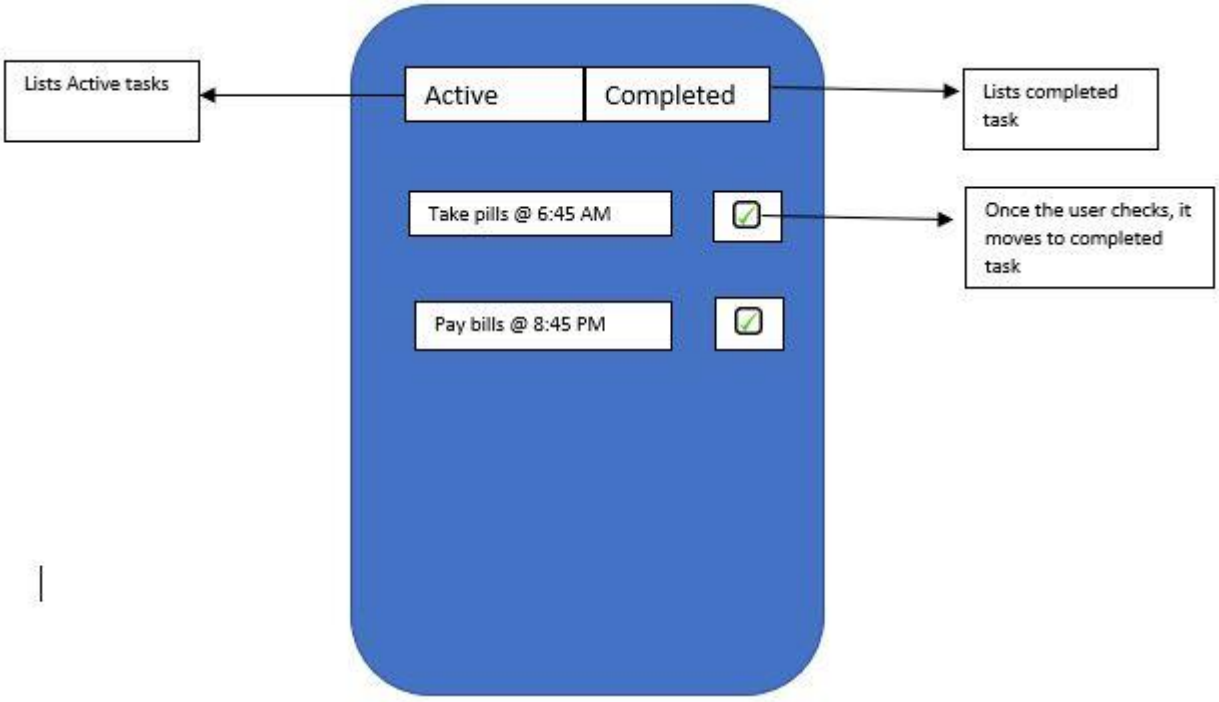

Figure 3 - Mockup screen of remind me feature

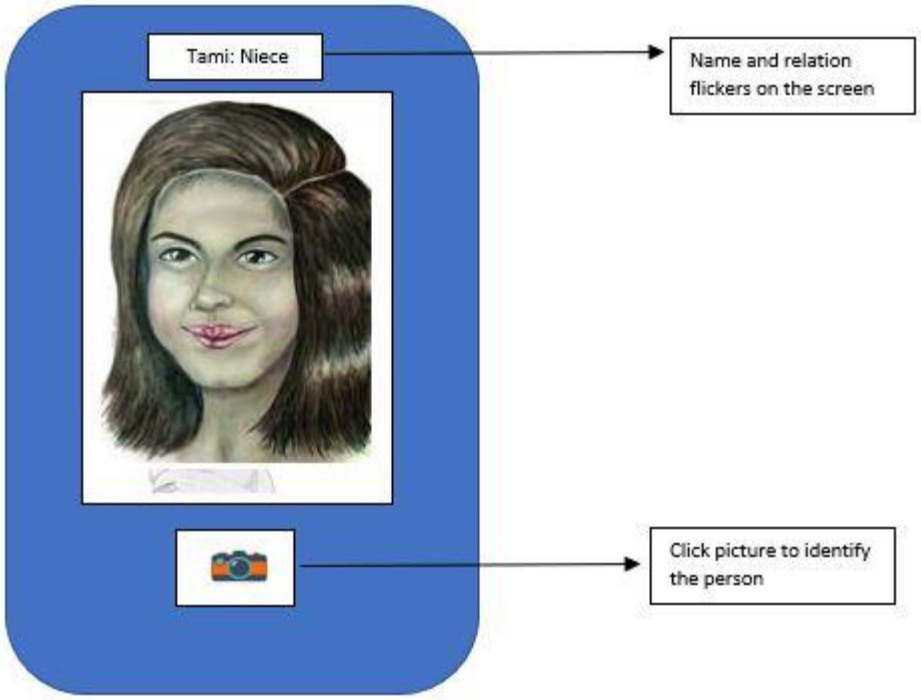

Figure 4 - Mockup screen of identify feature

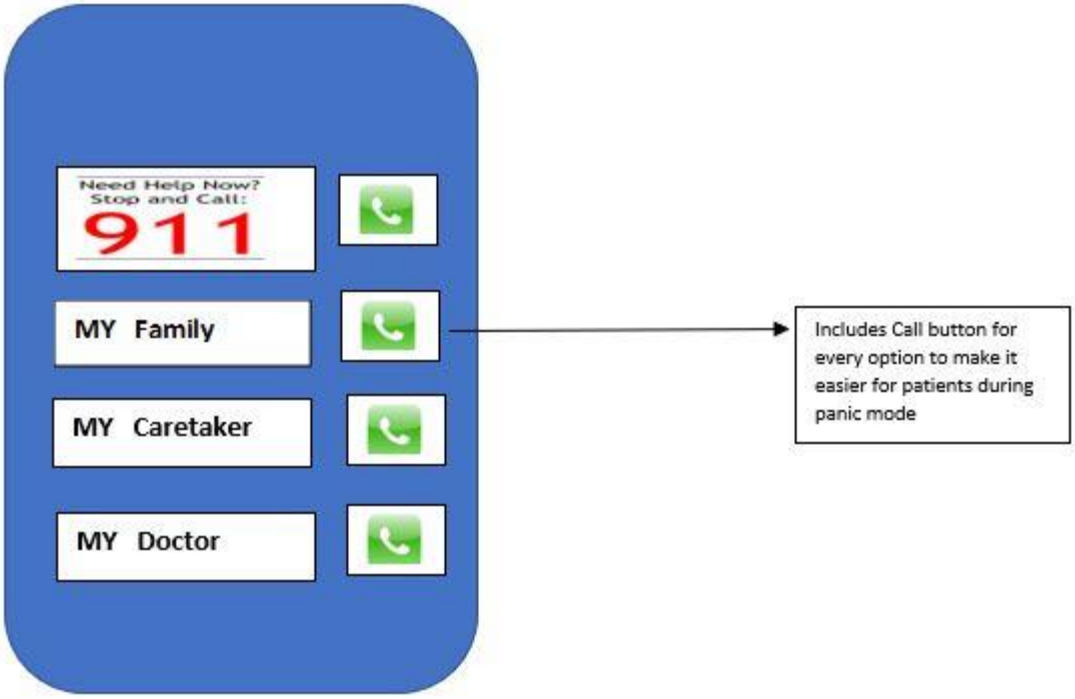

Figure 5 - Mockup screen helpline feature

3.2 Consent Form

Sample consent forms are provided on the Research Ethics website and may be used in conjunction with the information in the *Guidance* document to help you develop your consent form.

This study is being conducted as part of CSCI 6610; Human Computer Interaction.

We are attempting to understand if a helper app of our imagining could be useful to those with early stages of Alzheimer's or memory issues. To help answer this we are enlisting your help in this study. During this study we will ask to perform a series of tasks involving our prototype, during which you will be observed on your performance. Afterwards we will conduct a brief interview of your experience with our prototype.

If at any point you no longer feel comfortable participating in this study you can revoke your consent at any time and all data we have collected up until this point on you will be disposed of and you will suffer no negative consequences from withdrawing.

All data that we collect during this study will be kept anonymous to protect your privacy.
Please note, that as the data is collected anonymously, once you have completed the study you will not be able to withdraw your data as we cannot discern what data is yours.

I have read the explanation about this study. I understand what I am being asked to do and my questions about the study have been answered. I agree to take part in this study. I know that participating is my choice and that I can leave the study at any time.

_____ _____

PARTICIPANT'S SIGNATURE **DATE**

_____ _____

RESEARCHER'S SIGNATURE **DATE**

If you have any questions, comments, or concerns about your participation in this research project, please contact me, Miles Redgate miles.redgate@dal.ca

3.3 Recruitment Notice

RECRUITMENT NOTICE

Hello,

We are looking for participants for evaluating the prototype of our app that helps people with Alzheimer's by providing constant reminders and tracking their day to day activities, as well as support for minor struggles they might encounter.

Alzheimer's is a disease associated with memory loss and a person suffering from this disease will find it very difficult to remember and accomplish simple tasks of day to day life. This disease has become one of the major problems all over the world. The patients have a tough time remembering simple tasks daily. Alzheimer's affects the patients on 7 different stages. Our app Al-momentous is intended for the patients who are affected up to stage 4(the beginning stages of Alzheimer's).

The main objective of our study is to evaluate our app that helps users remember events, stay connected and engaged with friends and family and recognize faces of friends using face recognition technology. This app is intended to help users solve simple issues in their lives. Our team feels that this study is important as it could pave the way for helping out the patients whose memory is worsening over time. As there is no cure for this disease, we aim to improve their quality of life for as long as we can.

If you are interested, please reach out to us on absolutecontagious@dal.ca or +1-7828858585

4. Reference

[1] Studies, H. How to Determine the Right Number of Participants for Usability Studies: UX

matters. Uxmatters.com, 2019. https://www.uxmatters.com/mt/archives/2016/01/how-todetermine-the-right-number-of-participants-for-usability-studies.php.

[2] Timeless - A Mobile App for Alzheimer's Patients. Indiegogo, 2019.

https://www.indiegogo.com/projects/timeless-a-mobile-app-for-alzheimer-s-patients#/.

[3] Radebaugh, T. and Ward-Robinson, J. Cultural Diversity and Alzheimer Disease:

Introduction. Alzheimer Disease & Associated Disorders 16, (2002), S41-S42.

[4] Ulrich, J. Alzheimer changes in nondemented patients younger than sixty-five: Possible early

stages of Alzheimer's disease and senile dementia of Alzheimer type. Annals of Neurology 17,