PARTICIPANT CONSENT FORM

Title of Study: **Potential Benefits of Medication Dispensing System to Support Medication Adherence for Individuals Living at Home with Chronic Conditions**

Study Sponsor: **Centre for Aging and Brain Health Innovation (CABHI)**

Principal Investigator:
Mubashir Arain, Senior Consultant, Alberta Health Services
10301 Southport Lane, SW
Calgary – Southport Tower AB T2W 1S7
Telephone: 403-943-0783

Co-investigator:
Armghan Ahmad, Research and Evaluation Coordinator, Alberta Health Services

Why am I being asked to take part in this research study?

You have been invited to participate in this study because you are regularly taking more than five medications. A medication dispensing system called spencer might benefit you by helping you manage your medications. The researchers at Alberta Health Services expect that spencer might help you take your medications on time (this is called medication adherence). We need to test this to find out if it's true. That is why we need study participants like you to help us find out if spencer makes taking your medications on time easier.

Background

In Canada, studies report that two thirds of individuals aged 65 and older are prescribed at least five or more medications. Studies have also shown that patients with chronic conditions who take their medications on time show better symptom management and improved quality of life. But patients sometimes forget to take their medication on time. Due to factors such as the number of medications and the number of times they are required to take them.

Spencer is about the size of a toaster and can sit on a kitchen counter. Spencer reminds people when to take their medications on time by alerts you can see and hear. Spencer is connected to a specially trained pharmacist that helps make managing your medication schedule easier. Spencer might help individuals stay independent in their homes longer. To learn more you can visit www.meetspencertoday.com

Before you decide, one of the researchers will go over this form with you. You are encouraged to ask questions if you feel anything needs to be made clearer. You will be given a copy of this form for your records.

What is the reason for doing the study?

The reason for the study is to find out if spencer supports medication adherence. We will collect information on the benefits and challenges of using spencer. Then we will compare that information to the benefits and challenges of using other forms of medication management method (i.e., blister pack).

What will I be asked to do?

If you agree to take part in the study, you will be placed into either the intervention group or the control group. A computer will assign you to a group randomly, similar to tossing a coin. We have no control over which group you will be in. Participants in the intervention group will use the spencer system, provided and distributed by a company called Catalyst Healthcare, every day for 6 months. Participants in the control group will continue to manage their medications the way they do now. The study data for both groups will be collected over a 6-month period in Calgary, Alberta.
If you are in the **intervention** group:

You will get to try spencer and will have to use Sandstone Pharmacies at their Enhanced Care Solutions site during the study. This is because Sandstone pharmacists have been trained to use the spencer systems. They can remotely monitor and provide support as needed. They also use the Catalyst Healthcare system for filling your prescriptions and delivering them to your home.

Sandstone Pharmacies will take care of letting your physician and your current pharmacy know that you have agreed to be a part of the spencer study and will be switching pharmacy.

Before the study begins, a Sandstone pharmacist will help you set up spencer in your home. They will explain to you and one of your family members how to use it. To make sure the spencer is always working properly, you will have technical support available 24 hours a day, 7 days a week. Also, spencer lets you get your medications ahead of time if you need to go out or are going away. It also has a back-up battery, in case of a power outage. The steps of changing to Sandstone Pharmacies are below:

a. The research team will give your information to Sandstone Pharmacies so that they can contact you
b. The Pharmacy will work with you to pick the best day to get started with the study
c. The Pharmacy will contact your current pharmacy to transfer your prescriptions to the Sandstone Pharmacies
d. The Pharmacy staff will do a home visit and set up spencer for you. During this 45-60-minute visit;
    I. The Pharmacy staff will do a demonstration of how to use spencer
    II. They will ask a few questions to make sure you understand how to use it safely
    III. Explain how you will use it for ongoing medication support

Sandstone Pharmacies will deliver the spencer unit and your medications to you for the duration of the study with no delivery charges. However, prescription (medication) coverage is your responsibility as is the case with your current pharmacy. If you would like to keep using spencer after the study, it can be leased for a monthly fee of $100. This is a discounted rate negotiated between Alberta Health Services and Catalyst Healthcare for study participants only. If someone you know would like to use spencer for their medications it will available for a monthly leasing fee of $150.

We will also interview your caregiver and health care provider including the Sandstone pharmacist. The purpose is to know their views about you using spencer for medication management and its potential impact on your care.

If you are in the **control** group:

You will not get a spencer and will get your medications from your pharmacy and take your medications the same way you do now. You will be asked to keep a daily record of missed medications. We will keep track of your medication management for 6 months.

For all participants in both groups, we will:

1. Do an initial assessment

   We will do the first assessment at your home, and it will take about 30 minutes to one hour. This helps us understand your:

   - Current health status
   - Living arrangements
   - Caregiver support
   - Independence in carrying out daily tasks
   - Challenges for medication management

2. Track your medication adherence

   If you are in the intervention group, we will check your daily medication adherence data from the spencer system you are using. If you are in the control group, you will be recording the medications you missed each day.

3. Have a phone call once a month

   This is so we can check medication commitments, and ask about any changes in your health or healthcare needs. The call will take about 10-15 minutes.

Our research team will collect information from your health records kept by other healthcare providers such as your family doctor and specialists. We will also review emergency department visits, number of hospital admissions, home care visit record, assessments if you are currently using home care services, and pharmacy medication refill rates as part of the study. Information from these records will used for comparison purposes to fully understand the benefits of spencer to patients.

What are the risks and discomforts?

Spencer is approved by Health Canada and there are no known health risks to taking part in this study. During this study, if we find any new information that could change your decision to be a part of the study we will let you know.

If you are in the group using spencer, you will be asked to temporarily change your pharmacy. This could pose a risk of medication errors, or other harms related to a break in continuity of care. Sandstone Pharmacies will complete a full medication and care plan review with you to ensure continuity of the care you are receiving now.

What happens if the spencer stops working during the study?

As with any technology, it is possible that spencer might not work properly. It's also possible that you won't understand how to use the device properly. You will have access to 24/7 technical support.

If the spencer system fails, you will be able to access your medications by removing the refill box. The medication packets in the box are labelled with the names of the medications and the times you should take them.

What are the benefits to me?

Participants in the intervention group will receive a spencer device for the duration of the study. They will receive timely follow-ups, and, perhaps, receive pharmacist intervention. This might improve medication management and adherence. However, you may also not get any benefit from being in this research study. We will cover any additional costs related to the device.

If you are in the control group, you are not expected to get any benefit from being in this research study because you will continue to take your medications as before. This study may help other people with bettering their medication management in the future.

Do I have to take part in the study?

It is your choice to be in the study. You can change your mind at any time and stop being in the study. Your decision to withdraw will not affect the medical care that you are getting and we will stop collecting any new information about you. If you would like any data collected from you to be removed, please advise the research staff as soon as possible, before the research team starts to analyze the data. After the analysis has started it will be difficult to remove your information.

If you are uncomfortable with any questions, you don't have to answer them.

Will I be paid to be in the study?

You will not be paid, but there is no cost to you for participating. To thank you for your time and commitment, we'll give you a $50 Superstore gift card. You will receive this once the baseline assessment is completed.

Will my information be kept private?

During the study, we will be collecting information about you. The information that you share will be kept confidential and private. Any information that includes your name will not be used outside of the researcher's office and will not be published.

If you are assigned to use spencer, a Registered Nurse who is the Director of Clinical Outcomes at Catalyst Healthcare will view your medication adherence data for tracking and reporting purposes. Also, Sandstone pharmacists will see your health information. This is because they will be filling and delivering your prescriptions.

If you're in the control group, your current pharmacy will see your health information, as usual.

The University of Alberta Auditors and Human Research Ethics Board have the legal right to view the data.

We will do everything we can to make sure all your health information is kept private. All members of our research team and our collaborators (the pharmacists and nurse mentioned above) will follow Alberta Health Services data storage and safeguarding policy. Data will not be shared with any external party.

We will use data from the study for reports, publications, and presentations of research information. Data from the study will be used only in an aggregate form. Data we collect about you will be associated with an ID number. Your name will not be used. All collected data will be stored on a secure server at Alberta Health Services and destroyed after 5 years.

You may have a copy of the reports and publications if you wish.

By signing this consent form, you are saying it is okay for the study team to collect and use the information for study purposes.

What if I have questions?

If you have any questions about the research now or later, please contact the principal investigator, **Mubashir Arain**, by email at mubashiraslam.arain@ahs.ca or phone at (403) 943-0783.

The plan for this study has been reviewed by the Health Research Ethics Board at the University of Alberta. If you have any questions regarding your rights as a research participant, you may contact the **Health Research Ethics Board** at (780) 492-2615. This office has no affiliation with the study investigators.

How do I participate in the study?

If you would like to enroll in the study, please provide your name and contact information to our research coordinator, **Armghan Ahmad**, by email at armghan.ahmad@ahs.ca or phone at (403) 943-0185. The research team will contact you and let you know the next steps.

CONSENT

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Principal Investigator(s): Mubashir Arain (PhD) **Phone Number(s):** 403-943-0783
Study Coordinator: Armghan Ahmad (MPH) **Phone Number(s):** 403-943-0185

	Yes	No
Do you understand that you have been asked to be in a research study?	☐	☐
Have you read and received a copy of the attached Information Sheet?	☐	☐
Do you understand the benefits and risks involved in taking part in this research study?	☐	☐
Have you had an opportunity to ask questions and discuss this study?	☐	☐
Do you understand that you are free to leave the study at any time without having to give a reason and without affecting your future medical care	☐	☐
Has the issue of confidentiality been explained to you?	☐	☐
Do you understand who will have access to your study records including personally identifiable health information?	☐	☐
(Do you want the investigator(s) to inform your family doctor that you are participating in this research study? If so, give his/her name _____)	☐	☐
Future Contact Do you agree to be contacted for follow-up or to facilitate future research?	☐	☐
Use of my research information beyond this study Do you agree for your information to be securely stored at [Alberta Health Services] to facilitate future reuse?	☐	☐

Who explained this study to you? _____

I agree to take part in this study:

Signature of Research Participant _____(Printed Name) _____

Date:_____Signature of Witness _____

I believe that the person signing this form understands what is involved in the study and voluntarily agrees to participate.

Signature of Investigator or Designee _____ Date _____

THE INFORMATION SHEET MUST BE ATTACHED TO THIS CONSENT FORM AND A COPY GIVEN TO THE RESEARCH PARTICIPANT