Title: *Next-generation medication dispenser to improve care at home for community-dwelling elderly*

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Document updated on: April 17, 2018

NCT ID: Not yet assigned

Unique Protocol ID: I2P2: AceAge

1 INTRODUCTION

The prevalence of multi-morbidity (i.e., > 2 mental and/or physical conditions) in the elderly population is upwards of 60% (Salive, 2013). Patients with multi-morbidity are often prescribed multiple medications of varying doses to be taken at different times of the day. Furthermore, there is considerable evidence showing that non-adherence to prescribed medications can be as high as 50% among the elderly, especially among those with cognitive impairment (Conn, Taylor, & Miller, 1994). Non-adherence can lead to mismanagement of chronic diseases and it increases the risk of adverse drug reactions, physician consultations, emergency room (ER) visits and hospitalizations (Vermeire, Hearnshaw, Van, & Denekens, 2001). Overall, these factors have a significant impact on the health system, health care cost and patient quality of life.

Alongside medication non-adherence, polypharmacy is highly prevalent among the elderly and patients with multi-morbidity. Polypharmacy refers to the use of inappropriate or not clinically needed medications, which is a problem in itself as well as a potential contributor to medication non-adherence. In industrialized countries such as Canada, it is estimated that the elderly and patients with multi-morbidity take three times as many prescription medications as other patients and that they consume 70% of all non-prescription medications (Gallagher, Barry, & O'Mahony, 2007). As the number of prescription and non-prescription medications increases, the risk for adverse drug events increases dramatically.

Another contributing risk factor to drug-related complications is the physiology of aging. Specifically, there is significant inter-individual variation in medication responses that can be associated with age-related changes in pharmaco-kinetics and pharmaco-dynamics. Thus, careful individual medication dosing and monitoring is required. Finally, other high risk conditions such as having multiple health care providers (i.e., family physician and specialists)

who prescribe medication(s) and having many care setting/context transitions also increase the threat of medication errors.

Inappropriate use of medications in the elderly patient is of major concern to clinicians and public health authorities across Ontario, Canada and North America. 23% of patients have been found to experience an adverse event following discharge from the hospital. Adverse drug events are the most common type of adverse event, and found to be between 66% and 72% (Forster et al., 2004; Cornish et al., 2005). Of these, 24% are preventable and due to medication error (Baker et al., 2004). 33–69% of medication-related hospital admissions in the United States are due to medication nonadherence (Osterberg & Blaschke, 2005).

Optimal medication adherence has been linked to reduced hospitalizations and ED visits. In an investigation of the impact of medication adherence on hospitalizations among patients taking medications related to diabetes, hypertension, hypercholesterolemia, and congestive heart failure, it was found that hospitalization rates were significantly lower among patients with high medication adherence(Sokol, McGuigan, Verbrugge, & Epstein, 2005). Likewise, adherent patients are less likely to experience an ED visit (Blanchard, Madden, Ross-Degnan, Gresenz, & Soumerai, 2013).

Given the risks associate with poor adherence and the apparent contribution of good adherence to reducing hospitalizations and ED visits, interventions for promoting good adherence should be pursued. To this end, a number of devices have been developed to promote medication adherence, though with limited success due to reliability, cost, etc. The purpose of this study is to investigate the efficacy of the KARIE Automated Medication Delivery Device in enhancing medication adherence among a group of community-dwelling patients immediately following discharge from inpatient rehabilitation

2 METHODS

2.1 Design

This study will utilize a multi-site randomized controlled trial design. One week prior to discharge from inpatient rehab, consenting patients will be randomly assigned to receive medication self-management education only (SME) or medication self-management education + KARIE (SME+K).

2.2 Participants

Study participants will include MSK, amputee, neuro rehabilitation and Geriatric Functional Enhancement Service (GFES) inpatients currently receiving care at West Park Healthcare Centre (Toronto) with a home transition plan following discharge. Inclusion criteria will include:

- need to manage medications independently at home;
- stabilized on medication, as per pharmacist/physician discretion; and
- mild-moderate cognitive/physical impairments, as per OT assessment
- Montreal Cognitive Assessment (MoCA) score not less than 16

It is anticipated that 20% of West Park patients will be eligible for SME and will consent to participation in the experimental trial. With 25 patients per unit and an average length of stay of 4-weeks on the MSK, amputee, neuro rehabilitation units, it is anticipated that a recruitment target of 75 experimental and 75 control subjects could be reached within a 10-month time frame (25 pts x 3 units x 20% x 10 months = 150 pts). These 150 patients from West Park will be randomly assigned to the SME (n=75) or SME+K (n=75) group. To meet this target an assumption of 80% compliance will be made. Therefore, up to 94 participants per experimental arm will be recruited. GFES length of stay is comparatively longer at roughly 12 weeks. It is expected that fewer patients will be recruited from GFES, but will contribute toward meeting the recruitment target.

One hundred fifty study participants will be recruited from the CapitalCare CHOICE programs (AB) which assist seniors to continue living independently and in their own home longer by managing all their health requirements. CapitalCare CHOICE clients attend one of three day centres, one to five days a week, and receive services which include ongoing medical, psychological, and social support. The total census for the CapitalCare CHOICE programs is 202 clients and enrollment varies. Initial recruitment will significantly predict how quickly the target of 75 experimental and 75 control subjects can be reached. If after the initial recruitment period suggests challenges meeting the target within the study timeframe, recruitment will be opened up to the CapitalCare Adult Day Program, Laurier House, Post-Acute, Sub-Acute, and Restorative Care clients at CapitalCare's other centres. The focus of these programs is to maintain client independence and autonomy while supporting personal care needs.

2.3 Outcome Measures

Primary objective: Usability and feasibility

- Measures:
    - Self-Efficacy for Appropriate Medication Use Scale
    - Beliefs About Medication questionnaire (at baseline)
    - Satisfaction and acceptance questionnaire

Secondary objective: medication adherence

- Measures, Self-reporting:
    - Morisky Medication Adherence Scale
    - Medication Adherence Questionnaire
    - Brief Medication Questionnaire
    - 7-day recall
- Measures, Objective:
    - Electronic data collected by the KARIE device. Adherence may be calculated as the number of dispensed doses/ the total number of prescribed doses during the prescription period *100

3 Procedures

3.1 Recruitment

Potential West Park study participants will initially be identified by clinical staff referring to SME. Apparently appropriate subjects will be informed of the study by a member of their care team and, if interested, identified as wishing to receive additional information about the study during their initial meeting with the SME OT. The OT will briefly explain the nature of the study and request consent for the study research assistant (RA) to contact the patient to provide additional details of the study objective and procedures. The RA will arrange to meet with patient expressing an interest in participating in the study to obtain written consent (see Appendix A) and conduct baseline measures. The OT and pharmacist delivering the SMP will be blinded to group assignment.

Potential CapitalCare study participants will be identified by the research team Occupational Therapist. The Occupational Therapist (OT) will share this information with the CapitalCare research assistant (RA) who will be in regular contact. The RA will acquire consent and collect baseline data from the client (see inclusion criteria and measures for definitions).

The study RA, who will be blind to the assignment of the client to either intervention or control group, will approach the potential participant to explain the study, its purpose and aims to obtain informed consent for the study. As far as possible to maintain, the researcher will be unaware of the designation of the client to the Karie or control group.

3.2 Subject Training

3.2.1 Self-Medication Education Program

West Park has a “Self-Medication Education Program” policy in place which seeks to establish independent medication SM capacity during the inpatient stay. Eligibility criteria for SME include a need to manage medications independently at home; stabilized on medication, as per

pharmacist/physician discretion; and mild-moderate cognitive/physical impairments, as per OT assessment. To determine SME eligibility, an OT and pharmacist completes the Interprofessional Screening for Self Medication Readiness (Appendix B) to determine self-management capacity. Eligible patients then receive training by an OT, followed by a 5-day self-medication performance assessment (Appendix C) by an RN prior to discharge. Following discharge, these patients are often referred to receive 24 OT outpatient therapy sessions for 3-months, on average.

CapitalCare will adopt the West Park "Self-Medication Education Program" program and documentation for purposes of this study. To determine SME eligibility, an OT, Pharmacist, or RN will complete applicable portions of the Interprofessional Screening for Self Medication Readiness (Appendix B) to determine self-management capacity. Eligible clients then will receive training by an OT, followed by a 5-day self-medication performance assessment (Appendix C) by an RN.

3.2.2 Orientation to KARIE

Patients randomly assigned to receive SME+K will undergo Screening for Self Medication Readiness (Appendix A) to determine self-management capacity, will receive SME by an OT, followed by a 5-day self-medication performance assessment (Appendix B) by an RN prior to discharge, as described above (see "Self-Medication Program"). In addition, this group will receive orientation to the KARIE Automated Medication Delivery Device. Karie orientation will be integrated into SME and delivered by the study OT, Tiziana Bontempo.

For purposes of this evaluation of the AceAge medication dispensing device, the SME and recruitment strategy will provide for: 1) standardized eligibility assessment, training, and performance evaluation of SM capacity for experimental and control subjects, 2) introduction to the AceAge device in the inpatient setting for experimental subjects, and 3) standardized medication adherence assessment during the 3-month outpatient follow-up period.

3.3 Apparatus

3.3.1 KARIE

The KARIE device delivers medication with the right dose at the right time, but it also monitors medication adherence, sends reminder alarms and produces timely adherence and side effects reports for physician review. The KARIE device can receive customized messages from health care providers; for instance, the patient can be asked about side effect(s) and/or the efficiency of the prescribed medication. Capture of this critical information will improve the clinical team's capacity to optimize the pharmacological treatment of chronic diseases, to assist in managing polypharmacy and to detect earlier medication related problems allowing them to intervene quickly to prevent the need for physician consultations, ER visits and/or hospitalizations. The KARIE device uses the multi-dose pouch packaging that pre-organizes drugs specific to the patient. Information on the package is read by KARIE to automatically schedule medication dispense and notification times. The device is simple with a single load action and a single button. In addition, it has communication capabilities such that if a patient misses a dose dispense, a notification is sent to a family member or caregiver who can then remind the patient. The device can also produce reports for physicians regarding medication adherence, side effects, chronic disease control, and non-prescription medication use, so they can better manage chronic disease care in patients with multi-morbidity. The KARIE device works as follows:

1. Loading Medication:
    - Patient receives their medication pre-organized in a cartridge from their pharmacist;
    - The patient (or their informal caregiver) inserts the cartridge in the backside of the device;
    - The medication schedule is automatically loaded via 2D barcode; and
    - Device is ready to dispense.
2. Daily Use:
    - Device notifies the patient when it is time for each medication through an audible noise and visual light;

- Patient presses button to dispense the specific medication for that point in time;
- The device dispenses the correct medication and adherence data is collected
- Patient takes the medication and adverse events in time can be recorded; and
- Dose dispense times are logged by the device.

3. Forgetting Medication:
   - Device notifies the patient when it is time for each medication through and audible noise and visual light; and
   - If patient does not take medication for 40 minutes or at customized times, a notification is sent.
4. Patient-reported Outcomes:
   - Real-time data collection at time of dose dispense;
   - Customizable questions for study or medication relevancy; and
   - Create accurate, enriched datasets when combined with user log data.

3.3.2 Medication Adherence Log

Study participants in the SME and SME+K groups will be provided with a medication adherence log. Participants will be asked to complete a log entry with every scheduled medication dispense time. Participants will be asked to record the medications and the time they were taken. If a medication was missed, participants will be asked to leave the entry blank for that particular time.

3.4 Data Collection

The study RA will contact each study participant to arrange a data collection session within 24-48 hours prior to discharge. Data collection will include those scales identified in Outcome Measures above. Following discharge to the community, RAs will contact study participants via telephone on a bi-weekly basis to enquire about any missed medications. During these telephone contacts the RA and study participant will review the medication adherence log for the previous 2 weeks.

Data collection will be repeated at 3-months post-discharge. The RA will contact the participant 1-2 weeks prior to completion of the 3-month intervention period to schedule in in-home visit where post-intervention data collection will take place. In addition, the RA will collect participant medication adherence log.

4 ANALYSIS

A 2x2 repeated measures analysis of variance will be conducted to test for significant between-groups differences at baseline and post-intervention, as well as within-groups comparisons from baseline to post-intervention. An intention-to-treat analysis using last-observation-carried-forward will be used to account for subjects who do not complete the 3-month intervention.

We will follow qualitative analysis methods established in healthcare research: simple content analysis of survey results and inductive thematic analysis of interview results. With regard to survey and interview data, we will also conduct descriptive statistics across intervention and control baseline measures to assess the variability within measures, and bivariate association between measures of adherence. Results will be interpreted cautiously rather than considered definitive.

5. REFERENCES

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West Park
HEALTHCARE CENTRE

Informed Consent Form

Title of Study: Next-generation medication dispenser to improve care at home for community-dwelling elderly

Investigators:
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Purpose of Study: The purpose of the study is to determine whether clients using an in-home medication delivery device are more likely to take their medications as prescribed. Previous research suggests that patients with good medication adherence are less likely to be require visits to the Emergency Department and are less likely to be hospitalized. The KARIE Automated Medication Delivery Device will provide you with reminders when to take your medication and will dispense a small sealed envelope which will contain all the medications you require at a single time.

Description of Study: If you choose to participate in this study, you will be assigned to participate in either a usual care group or the KARIE Automated Medication Delivery Device group (KARIE). You will have an equal chance of being assigned to one group or the other. If assigned

to the usual care group you will receive your medications in a standard blister pack by PharmaSave (West Park) or a Pharmacist (CapitalCare). If assigned to the KARIE group you will receive the KARIE device to use in your home as well as your regular medications which will be dispensed by the KARIE device.

About KARIE: The KARIE device is about the size of a large telephone and can be placed at a location you find convenient (e.g., kitchen table, bed side, etc.). Your medication is pre-packaged as a strip of individual envelopes that is loaded into the back of the KARIE device. When it is time for you to take your medications(s), KARIE will beep and light up. You will then press a button on the front of KARIE to receive a single medication envelope with all the medications you should take at that time. KARIE will then reset itself for the next reminder time.

Risks and Benefits: We do not foresee any risks associated with participation in this study. You will receive all the medications you were prescribed at the point you were discharged from inpatient rehabilitation.

Confidentiality: The identity of all individuals who participate in this study will remain confidential. Once data collection is complete, the information will be entered into an electronic database. The original data collection sheets will be kept in a locked cabinet and subsequently destroyed after a period of six years. Each participant will be assigned a unique identifier in the database for purposes of administering the data. No names will appear in the database. The findings will be analyzed and reported in a medical journal.

This study has undergone ethical review and been granted approval by the Research Ethics Boards at West Park Healthcare Centre and CapitalCare.

Informed Consent: I have read and received a copy of the Patient Information sheet. The research study has been explained to me and my questions have been answered to my satisfaction. I understand that I may derive no personal benefit from participation in this study. I know that I may ask now, or in the future, any questions I have about the study. I have been assured that any records related to this study will be kept confidential. The information obtained will be entered into an electronic database, a unique identifier will be assigned and the original questionnaire will be destroyed after a period of six years. I understand that my participation is voluntary and that I am free to decide not to participate in this study or to withdraw from the study at any time. I understand that my decision not to participate in this study will not jeopardise my relationship West Park Healthcare Centre or CapitalCare and will have no influence on my medical management. At the end of the study a copy of the study results will be available to me upon request. I know if I have any concerns in the future about my rights as a research participant, I can call Dr. Ron Heslegrave, Chair, West Park Ethics Board at (416)217-3820 x2120

_____	_____	_____
Name of Participant	Signature	Date
_____	_____	_____
Person obtaining consent	Signature	Date

APPENDIX B

West Park HEALTHCARE CENTRE

Interprofessional Screening for Self Medication Readiness

Eligibility criteria	Yes	No	Initials	Date	Comments
1. Does patient need ot manage meds independently upon d/c?					
2. Is patient expected to stay at least 5 days?					
3. Does patient have aphasia?					
4. Does patient have dysphagia					
5. Admission date: _____					
Cognitive status:	**Yes**	**No**	**Initials**	**Date**	**Comments**
1. Orientation to day of week					
2. Orientation to approximate time of day					
3. Ability to tell time form clock					
4. Ability to follow a calendar					
5. Admission MOCA score: _____					
Physical status:	**Yes**	**No**	**Initials**	**Date**	**Comments**
1. Ability to open • Dossette box compartments • Medicine vials					
2. Ability to receive tablets from container					
3. Ability to ambulate or wheel self to nursing station independently (Level 2)					
Pharmacy/Nursing:	**Yes**	**No**	**Initials**	**Date**	**Comments**
Does patient consent to SMP?					
Ability to state home medication names/purpose?					
Previous non-compliance with meds?					

Evaluation:	Yes	No	Initials	Date	Comments
Eligible for SMP (all 'yes' except for shaded boxes; *at the discretion of the team)					If not, name interventions:

West Park HEALTHCARE CENTRE

SELF-MEDICATION PATIENT PERFORMANCE RECORD

❑ **LEVEL 1 (Minimum 48 hours)** ❑ **LEVEL 2 (Minimum 72 hours)** ❑ **Dosette** ❑ **Vial/Bottle** ❑ **Blister pack**

START A NEW PAGE WHEN:

progressing a patient to a new level* AND/OR *when changing medication containers (dosette vs. blister back vs. bottle)

Date yy/mm/dd	Time	Initials/Designation	Time	Initials/Designation	Time	Initials/Designation	Time	Initials/Designation
Day no. ❑ ___	❑ Independent ❑ Physical assistance ❑ Verbal cueing re: compartment ❑ (Level 2): Cueing to initiate ❑ Other: _____		❑ Independent ❑ Physical assistance ❑ Verbal cueing re: compartment ❑ (Level 2): Cueing to initiate ❑ Other: _____		❑ Independent ❑ Physical assistance ❑ Verbal cueing re: compartment ❑ (Level 2): Cueing to initiate ❑ Other: _____		❑ Independent ❑ Physical assistance ❑ Verbal cueing re: compartment ❑ (Level 2): Cueing to initiate ❑ Other: _____	

Date yy/mm/dd	Time	Initials/Designation	Time	Initials/Designation	Time	Initials/Designation	Time	Initials/Designation
Day no. ❑ ___	❑ Independent ❑ Physical assistance ❑ Verbal cueing re: compartment ❑ (Level 2): Cueing to initiate ❑ Other: _____		❑ Independent ❑ Physical assistance ❑ Verbal cueing re: compartment ❑ (Level 2): Cueing to initiate ❑ Other: _____		❑ Independent ❑ Physical assistance ❑ Verbal cueing re: compartment ❑ (Level 2): Cueing to initiate ❑ Other: _____		❑ Independent ❑ Physical assistance ❑ Verbal cueing re: compartment ❑ (Level 2): Cueing to initiate ❑ Other: _____	

West Park HEALTHCARE CENTRE

SELF-MEDICATION PATIENT PERFORMANCE RECORD

❑ **LEVEL 1 (Minimum 48 hours)** ❑ **LEVEL 2 (Minimum 72 hours)** ❑ **Dosette** ❑ **Vial/Bottle** ❑ **Blister pack**

Date yy/mm/dd	Time	Initials/Designation	Time	Initials/Designation	Time	Initials/Designation	Time	Initials/Designation
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Date yy/mm/dd	Time	Initials/Designation	Time	Initials/Designation	Time	Initials/Designation	Time	Initials/Designation
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