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Randomised controlled trial of pharmacist-led patient counselling in controlling hypoglycaemic attacks in older adults with type 2 diabetes mellitus (ROSE-ADAM): A study protocol of the SUGAR intervention

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ABSTRACT

Introduction: Hypoglycaemia is one of the most serious adverse effects of diabetes treatment. Older adults are at the highest risk to develop hypoglycaemia. Several studies have established the important positive role of educational interventions on achieving glycaemic control and other clinical outcomes, however, there is still a lack in studies that evaluate the impact of such type of interventions on hypoglycaemia risk in elderly patients with type 2 diabetes. The purpose of this research is to evaluate the effectiveness of pharmacist-led patient counselling on reducing hypoglycaemic attacks in older adults with type 2 diabetes mellitus.

Methods: and analysis: This study is an open-label, parallel controlled randomised trial, which will be conducted in the outpatient clinics at the largest referral hospital in the north of Jordan. Participants who are elderly (age \geq 65 years), diagnosed with type 2 diabetes mellitus, and taking insulin, sulfonylurea, or any three anti-diabetic medications will be randomly assigned to intervention (SUGAR Handshake) and control (usual care) groups. The SUGAR Handshake participants will have an interactive, individualised, medications-focused counselling session reinforced with a pictogram and a phone call at week six of enrolment. The primary outcome measure is the frequency of total hypoglycaemic events within 12 weeks of follow up. Secondary outcomes include the frequency of asymptomatic, symptomatic, and severe hypoglycaemic events, hypoglycaemia incidence, and time to the first hypoglycaemic attack. We will also conduct a nested qualitative study for process evaluation.

Ethics and dissemination: The Human Research Ethics Committee of the University of Lincoln and the Institutional Review Board of King Abdullah University Hospital approved this protocol. The findings of this study will be presented in international conferences and published in a peer-reviewed journal.

Trial registration number: The study protocol has been registered with [ClinicalTrials.gov](https://clinicaltrials.gov), NCT04081766.

Introduction

Background

Hypoglycaemia is the major limiting factor in diabetes management.¹ Hypoglycaemia has been found to be associated with cardiovascular events such as myocardial infarction, arrhythmias and cardiovascular mortality as well as cerebral complications such as dementia.²⁻⁶ Additionally, hypoglycaemia can impact patients' quality of life.⁷ Patients with moderate or worse symptoms of hypoglycaemia are less satisfied with their treatment and report poorer adherence to their medications.⁸ The great burden of hypoglycaemia is largely

presented by the considerable health care cost resulting from hospitalisations, ambulance services, emergency department visits, and absenteeism from work.^{9,10}

Older adults are the most susceptible age group to develop hypoglycaemia and to experience hypoglycaemia-related complications.¹¹ The correlation between ageing and hypoglycaemia in type II diabetes is multifactorial.¹¹⁻¹⁵ Factors such as physiological changes in elderly that would affect the pharmacokinetics profile of anti-diabetic drugs, comorbidities that affect heart and kidneys, nutrition changes and cognitive impairment that could affect concordance and compliance with treatment regimen.¹¹⁻¹⁵ As the population of older adults is increasing, globally; it is expected to see an increase in the prevalence of

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T2DM in older adults.^{16,17}

In Jordan, the prevalence of diabetes in people aged 60 years and over increased significantly over ten years period.¹⁸ It is estimated that the number of elderly persons in Jordan will be three times higher in 2050 than it was in 2017, consequently more older adults will be at risk of developing type II diabetes and diabetes-related complications.¹⁹ There are several studies on the association between hypoglycaemia and patient characteristics such as patients' perspectives and attitudes towards diabetes management skills, self-monitoring of blood glucose, and non-adherence to anti-diabetic medications in Jordanian population.^{20–23} However, there is a dearth of data on the interventions that could potentially prevent hypoglycaemia in such patients, especially the older population. Therefore, it is imperative to develop diabetes-related care strategies targeted to this broad population of patients to cope with the growing figures in the future.

In the context of diabetes, pharmacist-led care interventions appear to have a pivotal role in glycaemic control, improving self-care activities, medication adherence, improving quality of life, and reducing related complications.^{24–28} Pharmacist-led care interventions can be individualised to each patient to achieve glycaemic control.^{24,29,30}

However, a few randomised controlled trials (RCTs) have investigated the impact of such interventions on hypoglycaemia in adults diagnosed with T2DM.³¹ Although elderly people are considered heterogeneous group with different characteristics from younger adults, none of these trials has explored the effect of educational interventions in this age category. Jordanian pharmacy education equips the pharmacists with robust clinical knowledge and clinical skills to work with other healthcare professionals to provide optimal quality care to the patients.³² Therefore, the aim of this study is to evaluate the effectiveness of pharmacist-led patient counselling on preventing hypoglycaemia in older adults with T2DM.

Educational interventions are considered to be “complex” interventions compared with classic examples of drug interventions in RCTs.³³ That is an educational interventions' success or failure could be attributed to a myriad of factors besides the interventions' effectiveness. The factors such as the delivery of the intervention, understanding of the intervention by the patients and implementation of intervention would decide the fate of an educational intervention.³⁴ For this reason, a process evaluation is valuable to identify whether an intervention works and how, barriers for its implementation, and how to improve it in the future.³⁴ Undertaking qualitative studies to evaluate the interventions during the implementation stage helps in modifying the ongoing interventions as well as the study design to make them more feasible and effective.³⁵

Objectives

Primary objective

- To evaluate the effectiveness of an individualised, pharmacist-led educational intervention called (the SUGAR Handshake) in reducing hypoglycaemic attacks in older adults with diabetes for a duration of 12 weeks.

Secondary objectives

- To establish baseline characteristics that could potentially identify those elderly patients who are at a higher risk of developing hypoglycaemia.
- To conduct a nested qualitative study as a process evaluation to explore contextual factors affecting the implementation and outcomes of the study.

Methods

The methodology of this study is designed, conducted, and reported

according to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT)³⁶ and is presented in an appendix to the electronic version of this paper.

Study design

The study will be a single-centre, two groups, 1:1 parallel, open-label, pragmatic randomised controlled trial with a nested process evaluation embedded; and will be conducted in two clinics at a referral tertiary hospital in Jordan. Participants will be randomly assigned to either the intervention group hereinafter referred to as the “SUGAR Handshake” group or the control group. Fig. 1 illustrates the detailed study flow chart.

Setting

This study will be conducted in the endocrinology, cardiology, and diabetic foot care clinics at King Abdullah University Hospital (KAUH), a referral hospital in the north of Jordan.

Sample size

Heterogeneous definitions of hypoglycaemia and the frequent underestimation of hypoglycaemic episodes pose some challenges as the frequency of hypoglycaemic events is the primary factor in calculating the sample size.^{37,38} We referred to the most relevant study that used a similar outcome measure, methodology and intervention to our research to calculate the needed sample size.³⁹ The previous study found that the mean total number of hypoglycaemic attacks in the control and the intervention groups were 5.26 ± 6.5 and 2.58 ± 2.3 per patient in 24 weeks, respectively. We used the reported frequency of hypoglycaemic attacks in both groups to calculate the minimum required sample size. Therefore, we need to recruit at least 184 patients to achieve a significance level of 0.05 and a study power of 80%.⁴⁰ Accounting for 10% to compensate attrition rate and missing data, the final sample size wished to be recruited is 204 participants (102 in each group).

Participants and recruitment

We will recruit older adults who are 65 years and above, diagnosed with T2DM and being prescribed sulfonylurea, insulin, or any three anti-diabetic medications. Exclusion criteria include patients unable to understand instructions or to give consent, diagnosed with haemolytic anaemia or haemoglobinopathies, on palliative care for cancer, with advanced-stage or end-stage diseases who are terminally ill, diagnosed with psychosis or severe depression, or with life expectancy <6 months, impaired mental capacity, unwilling to take home glucose measurements or to use the glucose meter, or unwilling to return for follow up. Patients who have a partner or a first-degree relative who has been enrolled in the study, are excluded as well.

We will use two recruitment methods to reach potentially eligible patients: an advertisement placed in the reception room where patients wait for their appointments, and through direct identification of potentially eligible patients at the recruitment sites. HA will be responsible for recruiting participants in the endocrinology and diabetic foot care clinics meanwhile the research assistant (RA) will recruit from the cardiology clinics. HA and the RA will explain the trial purpose and processes and provide participant information sheets (supplementary file 1) to the interested patients. They will also confirm the eligibility of patients who are willing to participate and will ask them to sign a written consent form (supplementary file 2).

Recruitment has started in February 2020 and was suspended in March 2020 due to corona virus disease outbreak. Recruitment was resumed in June and is expected to be completed in November 2020.

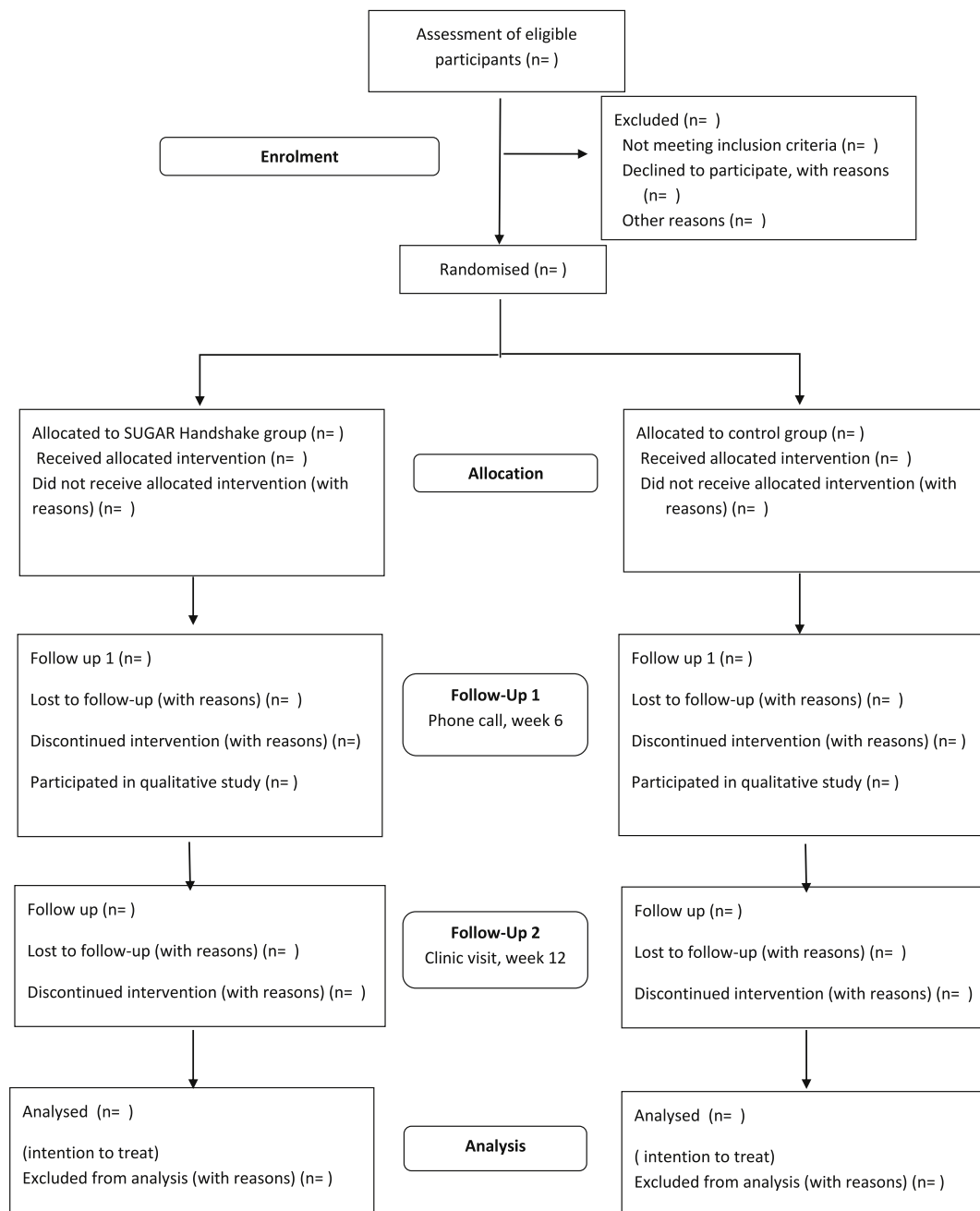


Fig. 1. Flow chart of participants during the study.

Randomisation and allocation

We will randomly assign participants to the intervention and control groups on a 1:1 basis. The random sequence will be generated using the website (www.randomization.com) to generate the randomisation schedule. Envelopes will be used to conceal the allocation and will be opened by the researcher sequentially at the time of each participant's enrolment. The study envelopes will contain the study name, the participants' codes, the group to which the participants are randomised. The randomisation sequence and the study envelopes will be prepared by a third independent party who will not be involved in the study. The envelopes will be closed and opaque and will be given to the researcher and the RA who are involved in conducting the study. The envelopes that will contain the group allocation will be kept in a locked cabinet in the hospital.

Blinding

Since this is an open-label study, the patients and the data collectors will not be blinded to the assigned group. Eligible patients will be informed about the purpose of the study and the study-related activities before they sign the consent form. Proper measures will be taken along the trial duration to minimise performance and ascertainment bias that may result from unblinding participants.

All participants will be unblinded to the study groups and to the real purpose of the trial at the follow-up visit that would mark the end of the trial. Additionally, participants who are assigned to the control group will receive the SUGAR Handshake intervention at the follow-up visit.

Intervention group (SUGAR handshake)

The educational intervention, the SUGAR Handshake, is designed to promote behavioural change to prevent hypoglycaemia. We applied the principles of the behaviour wheel theory (BCW) to design the intervention.⁴¹ Our educational intervention would enhance the physical and psychological capabilities of the patients through improving their knowledge and skills in managing and preventing hypoglycaemia. The intervention would also lead to the behavioural change by a conducive environment to promote behaviour change by addressing the physical and cultural needs of the patients.

We have structured the reporting of the intervention in line with the TIDieR (Template for Intervention Description and Replication) checklist and guide.⁴² Participants assigned to the SUGAR Handshake group will receive individualised counselling regarding hypoglycaemia in addition to the usual care provided at the trial sites. The intervention is designed by HA who is a pharmacist with prior work experience in patient counselling and pharmacist-related clinical services. HA has trained the RA on delivering the intervention. The intervention is delivered in two steps i.e., a face-to-face conversation at the enrolment visit followed by a phone call six weeks later.

Step one: face-to-face conversation at the enrolment visit

Participants in the intervention group will have a 35–45 min conversation with HA/RA to receive the SUGAR Handshake intervention. It is designed to meet the physical and cultural needs of the participants while considering the individual needs of each participant. To facilitate the learning and retaining the information by the elderly, we have collated the contents of the intervention under five main domains to symbolise a handshake. (See Fig. 2).

The SUGAR Handshake intervention will cover comprehensive strategies to prevent and handle hypoglycaemia with instructions related to anti-diabetic medications and managing drug-related problems. Table 1 illustrates the contents of the SUGAR Handshake intervention about each domain.

At the end of the face-to-face session, participants will be provided with the SUGAR Handshake pictogram containing the main recommendations (Fig. 3). The pictogram is designed to be served as a visual reminder of the SUGAR Handshake intervention and as a reference throughout the duration of the trial. The fourth and fifth domains of the

SUGAR Handshake pictogram are designed to allow individualisation of the intervention.

Step Two: Phone call at the 6th PWeek.

Participants will receive a 20-min follow up call at week six of enrolment; so that the first step of the intervention would be reinforced as well as participants' queries/questions would be answered.

Participants will also be asked about the number and timing of having hypoglycaemic attacks during the first six weeks in the trial to reconsider modifying the intervention components.

Control group

Participants in this group will be offered guidance on hypoglycaemia diagnosis and the proper use of the glucose meters in addition to the usual care. They will also be provided with instructions on hypoglycaemia treatment. As participants in both groups will receive the same information regarding hypoglycaemia recognition, they will have similar ability to recognise hypoglycaemic attacks. At week 6 of enrolment, participants will receive a phone call to remind them of using the glucose meters and documenting hypoglycaemic attacks.

Of special note, participants who complete the trial duration will receive the intervention at the debrief visit and after returning the hypoglycaemia diaries.

Hypoglycaemia documentation

All participants in both groups will be given glucose meters and test strips with a demonstration on proper use to measure their blood glucose levels at morning before breakfast daily for 12 consecutive weeks. They will also be handed diaries and instructed to document their daily fasting blood glucose levels, frequency of experiencing hypoglycaemia symptoms, and frequency of severe hypoglycaemic episodes during the follow-up period (supplementary file 4 shows the hypoglycaemia diaries). Diaries will be collected from participants during their follow up visit on the 12th week of their enrolment in the trial.

Data collection and storage

Data will be anonymised, encrypted and saved in a password protected folder on a safe server i.e., using the University of Lincoln's OneDrive with access limited to the research personnel (supplementary

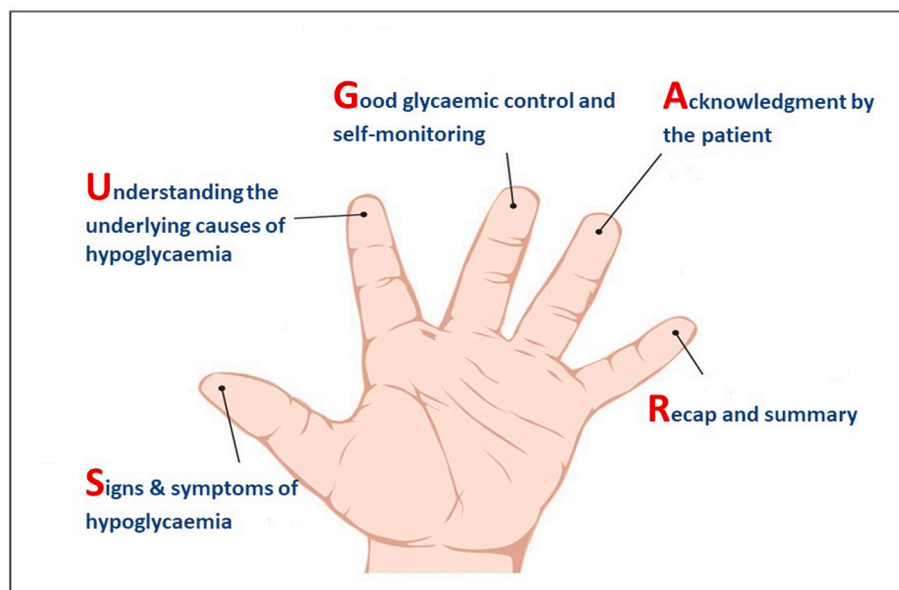


Fig. 2. Domains of the SUGAR handshake intervention.

Table 1
Description of the educational contents in the SUGAR Handshake intervention.

Domain	Contents
Signs and symptoms of hypoglycaemia	Recognising hypoglycaemic attacks according to symptoms
Understanding the underlying causes of hypoglycaemia	Modifiable factors potentiating the risk of hypoglycaemia Strategies to avoid/minimise these factors
Good glycaemic control and monitoring	Self-monitoring of blood glucose Individualised glycaemic targets Glucose meter use Frequency and timing of blood glucose measurements Recognising hypoglycaemic attacks according to blood glucose levels Anti-diabetic medications Indication and regimen Time of administration Dosing considerations (e.g. dose titration) Importance of medication adherence and missed doses handling Method of administration (e.g. insulin pens) Drug-drug interactions that may potentiate the hypoglycaemic effect lab tests monitoring (e.g. kidney function test) Storage conditions Managing drug-related problems Lifestyle recommendations Regular number and time of meals Consistent carbohydrate-containing food Alcohol consumption restriction Intensive physical activity avoidance Driving Hypoglycaemia and hyperglycaemia treatment
Acknowledgement by the patient	Reassuring patient agreement on the recommendations Patient recall the main strategies to recognise, avoid, and treat hypoglycaemia
Recap and summary	Summarising the intervention in 5 main points: symptoms and blood glucose measurement causes of hypoglycaemia handling antidiabetic medications lifestyle recommendations hypoglycaemia treatment

file 4 shows the data collection form). Electronic data will be maintained in storage for a period of 1–3 years after completion of the study.

Outcome measures

Primary outcome

Total hypoglycaemia. Total hypoglycaemia is defined as the number of total hypoglycaemic attacks per person per 12 weeks in both groups. Total hypoglycaemia will be calculated as the summation of symptomatic, asymptomatic, and severe episodes experienced by the participant during the follow-up period. More often asymptomatic hypoglycaemic events remain undetected; hence they are under-reported. Moreover, Hypoglycaemia unawareness is common in elderly T2DM patients.¹² Therefore, we anticipate that the rate of total hypoglycaemia is more representative to reporting the effect of the intervention rather than considering one type only.

Secondary outcomes

Severe, symptomatic, and asymptomatic hypoglycaemia. Types of hypoglycaemia are reported separately as the number of episodes per person per 12 weeks in both groups (Table 2). We identify types of hypoglycaemia in line with the definitions presented by a report of a workshop of the American Diabetes Association (ADA) and the Endocrine Society.⁴³ We chose this categorisation over others because health care professionals mainly follow the ADA guidelines for diabetes management in Jordan. Additionally, it is impractical for DM patients to measure their BG levels frequently to diagnose hypoglycaemia. Hence, it is imperative to account for both symptomatic and asymptomatic types of hypoglycaemia.

We will use diaries to measure types of hypoglycaemia and we will ask participants to fill in the diary on a daily basis for 12 weeks. Participants will be asked to fill in the diary with the date of each day and the fasting blood glucose reading. Additionally, they will be asked to tick on the boxes for every time they experience severe hypoglycaemia, symptoms of hypoglycaemia at the time of fasting blood glucose measurement, and symptoms of hypoglycaemia during the rest of the day. Participants will document a symptomatic attack if the symptoms resolve after receiving the corrective actions.

The rate of each type of hypoglycaemia will be measured according to the hypoglycaemia diaries filled by the participants. Severe hypoglycaemia will be measured directly according to the number of times a participant ticks on the diary the boxes that indicate a severe attack. Asymptomatic attacks will be measured as the number of times a participant records fasting blood glucose of 70 mg/dL or less without ticking on the boxes of experiencing symptoms of hypoglycaemia at the time of measurement. Symptomatic attacks will be measured as the summation of the number of times the participant experiences symptoms of hypoglycaemia at the time of fasting blood glucose measurement and during the day.

Proportions of patients experiencing hypoglycaemia. Percentages of patients experiencing at least one hypoglycaemic attack of any type at 3 months after randomisation in both groups.

Time to the first hypoglycaemic attack. Time to experience the first hypoglycaemic attack, measured as the number of the day when a participant will experience the first hypoglycaemic attack of any type after randomisation.

Process evaluation

We will carry out a nested qualitative process evaluation in line with the Medical Research Council (MRC) framework.⁴⁴ The process

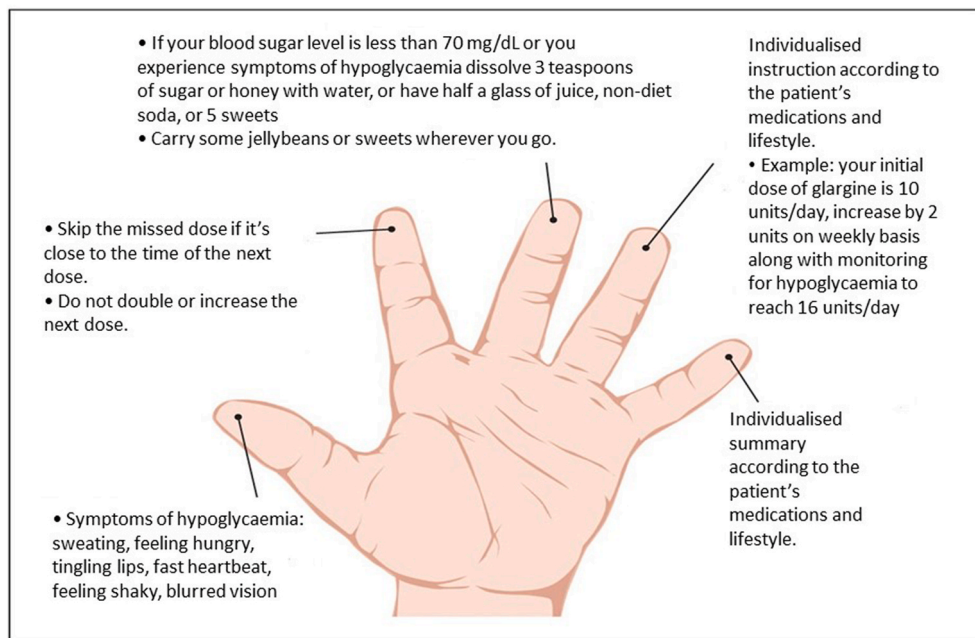


Fig. 3. SUGAR handshake pictogram.

Table 2
Definitions of hypoglycaemia types.

Type of Hypoglycaemia	Definition ^a
Severe	<ul style="list-style-type: none"> - requiring the assistance of another person to administer carbohydrate and glucagon or take any other corrective actions - accompanied by neurological recovery after the corrective actions
Symptomatic	<ul style="list-style-type: none"> - presence of typical symptoms such as sweating, dizziness, light-headedness, tremor, hunger, headache - presence or absence of plasma glucose concentration ≤ 70 mg/dL (≤ 3.9 mmol/L)
Asymptomatic	<ul style="list-style-type: none"> - absence of typical symptoms - measured plasma glucose concentration ≤ 70 mg/dL (≤ 3.9 mmol/L)

^a According to the ADA guidelines.

evaluation aims at identifying the contextual factors affecting the implementation of the study and the delivery of the intervention, what worked and what didn't, and how the study could be improved in future research.

We will collect qualitative data using semi-structured interviews from a handful of participants in each study group. We have prepared the interview guide (Table 3) based on the objectives of the study and the MRC domains for process evaluation.

Statistical analyses

All analysis will be performed on an intention to treat basis. The analysis will include all participants randomised regardless of their compliance with the study protocol. A secondary per-protocol analysis will be conducted including participants who are compliant to 80% or more of the study protocol.^{45,46} The missingness in the primary outcome will be handled under the assumption of "missing at random" rather than "missing completely at random", because we are expecting that the probability of missing data depends on observed covariates or outcomes rather than unobserved data. Therefore, the method chosen to handle missing data in the outcomes is multiple imputations.^{47,48}

Descriptive analysis will be used across randomised groups and

Table 3
Interview schedule.

1. Introduction You have previously read in the participant information sheet that we are conducting a phone interview as a part of this study and you accepted to participate in it. Therefore, I would like to ask you some questions about your experience with the study processes that have been provided to you at the inclusion visit. The information will help us in improving several aspects of the study. The interview should take about 10 min. Are you available to respond to the questions at this time?
2. I would like to start by asking: how do you describe your participation in the study so far? If needed, the interviewers may explain the question by the follow-up question: How do you rate your participation in the study from good to poor and why?
3. What has worked for you from the study processes that you were asked to do? - why do you think they have? what hasn't worked for you from the study processes that you were asked to do? - why do you think they haven't?
4. From your perspective, how the study could be improved? Please consider any aspects of the study that you think could be improved.
5. At the end, I would like to thank you for taking part in this interview. If you have any questions or concerns, please contact me on my mobile number provided in the participant information sheet.

quantitative analysis will be conducted in RStudio version 3.4.2 (28-9-2017).⁴⁹ Continuous variables will be presented as means, standard deviation, median and interquartile range, meanwhile, categorical variables will be presented as frequencies and percentages. The randomised groups will be examined and compared for all variables. Categorical variables will be evaluated using the chi-square test. Continuous variables will be tested for normality and based on the distribution of the data, appropriate parametric or non-parametric tests will be used. For example, paired *t*-test or Wilcoxon test would be applied to assess the differences in baseline variables between both groups and between participants who completed the trial as well as the participants who will be lost to follow up.

The primary and secondary outcomes (total and types of hypoglycaemic attacks) will be measured across the randomised groups and compared using the analysis of covariance (ANCOVA), and the appropriate parametric or non-parametric tests dependent on the normality of distribution. Subgroup analysis will also be performed using interaction terms in regression models.

We will use logistic regression analysis to examine associations between the categorical outcome variable (frequent vs infrequent hypoglycaemia episodes) and independent variables such as sex, age, educational level, living arrangements, duration of diabetes, number of current medications, experiencing previous hypoglycaemia, the status of self-monitoring of blood glucose, types of anti-diabetic medications, baseline HbA1c and interactions between the independent variables. The findings will be also presented as odds ratio and 95% confidence intervals. A *P* value of less than 0.05 will be considered statistically significant. Hypoglycaemia rates will be described with Kaplan-Meier survival curves, considering the time to the first hypoglycaemic attack as the outcome measure.⁵⁰

Qualitative data analysis

The interviews will be audio-recorded then transcribed and translated into the English language. We will use the thematic analysis approach to analyse the collected data for process evaluation.⁵¹

Patient and public involvement

The SUGAR Handshake intervention was designed by the researchers as a result of HA's previous experience in counselling the target population in Jordan about hypoglycaemia. Patients contributed in shaping the intervention by reporting feedback on the instructions that helped them the most to avoid hypoglycaemic attacks; which were mainly related to anti-diabetic medications. Furthermore, consultation of the health care providers working at the trial site played a role in the study design (schedule of follow up visits and recruitment rate).

Ethics and dissemination

Ethical approval and trial registration

The study protocol has been approved by the Human Research Ethics Committee of the University of Lincoln, United Kingdom (approval number: 2019-0170) and the Institutional Review Board of KAUH, Jordan (approval number: 13/3/1376). The ROSE-ADAM study was registered at clinicaltrials.gov (NCT04081766).

Protocol amendments

An ethics amendment for Version 5 of the protocol was approved in June 2020. If it is found there is a need for protocol amendments through the embedded evaluation process, the changes will be discussed by the supervisory team and will be communicated in writing to the Human Research Ethics Committee of the University of Lincoln and the Institutional Review Board of KAUH.

Dissemination of findings

Upon completion of the study, we will provide the trial site with an executive summary of the findings in the form of a report. Participants would be able to get the results of the study from their health care professionals at the trial site no later than one year after the end of data collection. We are planning to disseminate the study outcomes through peer-reviewed publications and presentations in conferences. We will comply with the authorship eligibility guidelines of the International Committee of Medical Journal Editors.

Discussion

This pragmatic RCT will be the first to determine the effectiveness of a pharmacist-led educational intervention, the SUGAR Handshake, to reduce events of hypoglycaemia for elderly adults with T2DM, with embedded process evaluation. The impact of educational interventions on controlling hypoglycaemia in patients diagnosed with T2DM has been inconclusive. That is some studies have shown positive results, meanwhile, others have failed to show such results.^{39,52-56} Elderly

patients are considered underrepresented age group and they are usually excluded from clinical trials about diabetes.⁵⁷ Studies which assessed the effectiveness of educational interventions on hypoglycaemia in patients with T2DM have either excluded elderly patients or included them with the young adult age groups.^{39,52-56} This study specifically investigates the effect of counselling on older adults with T2DM.

A major strength of this trial is the SUGAR Handshake components. The intervention is designed to be simple and tailored to the needs of elderly patients. Furthermore, this intervention adopts patient-centred approach in individualising instructions and shared-decision making with the participants based on their needs. Implementing this approach has proven to improve clinical outcomes, disease management, and controlling hypoglycaemia among patients with diabetes.^{58,59}

The SUGAR Handshake intervention is designed to be pragmatic and to facilitate transferability of evidence into practice. Therefore, pharmacists can easily deliver it to the patients in different working positions including hospitals and community pharmacies. Moreover, the delivery of the SUGAR Handshake intervention is cheap and will not cost an extra burden on patients. Previous studies concerning the attitudes, religious beliefs, and self-management skills amongst patients with T2DM helped in assuring the appropriateness of contextual and cultural delivery as well as the implementation of the study and the SUGAR Handshake intervention.²⁰⁻²³ Using blood glucose/hypoglycaemia diaries to objectively report and measure several types of hypoglycaemia is another strength. This will facilitate a more accurate measurement of hypoglycaemic events where the concern that patients may forget to report the experienced episodes is reduced.

A plausible limitation that warrants consideration is the short follow up duration (12 weeks), which may make it difficult to examine the sustainability of the intervention effect. However, we anticipate that this duration will decrease the dropout rate. Moreover, we expect the effect of our intervention to last up to at least six months as concluded by a previous trial.³⁹ Another concern is the enrolment of relatives into different groups upon randomisation, which will introduce contamination bias. Therefore, if a patient happens to have a relative who has already participated in the trial, he would be excluded. Additionally, participants may not fully adhere to the intervention during the follow-up period. For this reason, they will receive a phone call reminder at week six of enrolment. Individualising the intervention according to each patient's lifestyle and potential causes of hypoglycaemia will enhance the adherence to the intervention as well.

As this is an open-label study, performance bias and ascertainment bias may result from unblinding participants and the data collectors, respectively. Participants in the control group may be less adherent to the trial protocol and more likely to withdraw from the trial. However, efforts will be made to standardise the trial protocol, frequency and time of follow up, and treatment of experienced hypoglycaemia across both groups to minimise performance bias. We also anticipate that the objective measurement of the outcomes would minimise ascertainment bias.

The prevalence of diabetes in Jordan has been growing rapidly to reach 23.7% in 2017.⁶⁰ In light of the lack of awareness regarding diabetes diagnosis, causes, and management we would expect a further increase in the number of Jordanians who are diagnosed with diabetes and who would suffer from diabetes-related complications.^{20,60} While pharmacists are easier to access than physicians, a possible strategy to mitigate the burden of diabetes is to establish and support the pharmacist-led, patient-oriented services.⁶¹

We speculate that the findings of this trial may be valuable to patients with diabetes, pharmacists, health care professionals, pharmacy students, and health organisations nationally, regionally, and globally.

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Provenance and peer review

Not commissioned; externally peer-reviewed.

Data sharing statement

As the manuscript refers to a study protocol, there are no available datasets yet.

Patient consent for publication

Not required.

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Declaration of competing interest

None.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.sapharm.2020.07.012>.

Abbreviations

ANCOVA Analysis of Covariance
BCW Behaviour Wheel Theory
KAUH King Abdullah University Hospital
MRC Medical Research Council
PhD Doctor of Philosophy
RA Research Assistant
RCT Randomised Controlled Trial

SPIRIT Standard Protocol Items: Recommendations for
Interventional Trials
T2DM Type 2 Diabetes Mellitus
TIDieR Template for Intervention Description and Replication

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