Examining Share plus A Continuous Glucose Monitoring plus Data Sharing Intervention in Older Adults and Their Care Partners: Protocol for a Pilot Study

Nancy A. Allen, Cynthia A. Berg, Eli Iacob, Bruno Gonzales, Jonathan E. Butner, Michelle L. Litchman

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Nancy A. Allen[1*] PhD; Cynthia A. Berg[2*] PhD; Eli Iacob[1*] PhD; Bruno Gonzales[1*] BA; Jonathan E. Butner[2*] PhD; Michelle L. Litchman[1*] PhD

[1]University of Utah College of Nursing Salt Lake City US
[2]University of Utah Department of Psychology Salt Lake City US
[*]these authors contributed equally

Corresponding Author:
Nancy A. Allen PhD
University of Utah
College of Nursing
2000 East 10 South
Salt Lake City
US

Abstract

Background: Older adults with type 1 diabetes (T1D) are increasingly turning to care partners (CP) as resources to support their diabetes management. With the rise in diabetes technologies, such as continuous glucose monitoring (CGM), there is great potential for CGM data sharing to increase care partner involvement in a way that improves a person with diabetes (PWD) glucose management and reduces distress.

Objective: The specific aims of this paper are to (1) evaluate feasibility, usability, and acceptability of the Share plus intervention compared to the CGM Follow app plus diabetes self-management education and support (DSMES); (2) evaluate the effect of Share plus intervention on time-in-range (primary outcome) and diabetes distress (secondary outcome); and (3) explore differences between groups in PWD and CP dyadic appraisal and coping, quality of life, diabetes self-care, and CP burden at 12 and 24 weeks and associations of dyadic variables on outcomes.

Methods: This is a protocol for a feasibility pilot study. Older adults with T1D and their care partner (N=80 dyads) will be randomized 1:1 to the Share plus intervention or Follow+DSME. The evaluation is guided by the dyadic coping model. Patient-level effectiveness outcomes (time-in-range, hemoglobin A1c, diabetes distress, diabetes appraisal, coping, quality of life, diabetes self-care behaviors, and care partner burden) will be assessed, using patient-reported outcomes measures and a home hemoglobin A1c test kit. PWD-level and CP-level acceptability and feasibility will be assessed using surveys and interviews.

Results: This study is supported by the National Institute of Diabetes and Digestive Disorders. The study procedures have been approved. Recruitment and enrollment started in August 2023.

Conclusions: To our knowledge, this will be the first randomized control pilot to evaluate both feasibility and effectiveness outcomes for virtually-delivered Share plus intervention for older adults with T1D and their CP. This research has implications for CGM data sharing in other age groups with T1D and type 2 diabetes. Clinical Trial: NCT05937321

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Examining Share *plus* A Continuous Glucose Monitoring plus Data Sharing Intervention in Older Adults and Their Care Partners: Protocol for a Pilot Study

Nancy A. Allen, PhD, ANP-BC, Cynthia A. Berg, PhD, Eli Iacob, PhD, Bruno Gonzales, BA, Jonathon Butner, PhD, Michelle L. Litchman, PhD, FNP-BC

1	**Nancy A. Allen, PhD, ANP-BC** University of Utah, College of Nursing 10 South 2000 East Salt Lake City, UT 84060 ORCiD: 0000-0001-7358-2265 X: @NanAllenUT
2.	**Cynthia A. Berg, PhD** University of Utah, Department of Psychology 380 S. 1530 E. Salt Lake City, UT 84112 ORCiD: 0000-0002-5693-4561 X: @CindyBergLab
3	**Eli Iacob, PhD** University of Utah, College of Nursing 10 South 2000 East Salt Lake City, UT 84060 ORCiD: 0000-0003-1617-0314
4.	**Bruno Gonzales, BA** University of Utah, College of Nursing 10 South 2000 East Salt Lake City, UT 84060 ORCiD: 0000-0001-8808-4947
5.	**Jonathan E. Butner** University of Utah, Department of Psychology 380 S. 1530 E. Salt Lake City, UT 84112 ORCiD: 0000-0002-8747-5708
6.	**Michelle Litchman, PhD, FNP-BC** University of Utah, College of Nursing 10 South 2000 East Salt Lake City, UT 84060 ORCiD: 0000-0002-8928-5748 X: @MichLitch Email: michelle.litchman@nurs.utah.edu

Keywords: diabetes technology, continuous glucose monitor (CGM), type 1 diabetes (T1D), older adults, data sharing, telehealth

Corresponding Author: Nancy A. Allen PhD, ANP-BC University of Utah College of Nursing, 10 South 2000 East, Salt Lake City UT 84112, Nancy.allen@nurs.utah.edu

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Abstract

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ClinicalTrials.gov: https://clinicaltrials.gov/study/NCT05937321.Keywords: Type 1 Diabetes, Older Adults, Continuous Glucose Monitoring, Data Sharing, Dyadic Coping

Introduction

Type 1 diabetes (T1D) is a significant public health problem, with increasing numbers of adults now living into late adulthood.[1] T1D self-management requires a number of daily diabetes tasks including checking blood glucose (either through a blood glucose meter or a continuous blood glucose monitor (CGM)) and administering insulin to account for changes in food intake and exercise. Older adults with T1D are at increased risk for hypoglycemia, hyperglycemia, and glucose variability that may result in seizures, falls, and myocardial infarctions.[2,3] These risks are due to a number of factors including reduced awareness of hypoglycemic warning symptoms, reduced hormonal counter-regulatory response, and changes in dexterity, visual acuity, cognitive function, depression, and anxiety that may prevent affected individuals from taking corrective actions.[3,4]

Care partners (**CP**; e.g., spouse, adult child, romantic partner, friend) can serve as important resources for older adults living with T1D in reducing these risks to self-management.[5-9] Over half of adults with diabetes have an unpaid CP who regularly assists with diabetes management[8] and age-related changes often increase a person with diabetes' (PWD) need for CP assistance. One tool that is available to PWD and their CP to reduce harmful glucose levels is real-time CGM. A CGM transmits glucose trend data to the smartphone of a PWD and provides predictive alarms before problematic and potentially dangerous hypo- and hyperglycemia levels.[10] Recommendations for standards of care in diabetes[11] now include the use of CGM with older adults with T1D to address increased risks of hypoglycemia. PWDs are given glucose goals of 70-180 mg/dL, the percent of time spent within this range is called time-in-range (**TIR**), an important metric for evaluating glucose targets.[12,13] In older adults, CGM is effective at decreasing glucose variability, with older adults highly adherent to wearing CGMs.[20,21] The data provided by the CGM can now be shared with a CP's smartphone to facilitate diabetes support for the PWD.[14] Yet, few older adults and CPs are sharing data with CGMs.[15]

There is great potential for CGM data sharing to increase CP involvement in a way that improves PWD's glucose targets and reduces distress. For instance, the free data sharing app, Dexcom Follow,[16] allows CGM readings to be displayed on the smartphone or smartwatch of PWD and their selected CP. Follow also allows the user to see CGM glucose levels and receive predictive hypo- and hyperglycemia alerts. Additional apps such as the free Dexcom Clarity app, [17] use the data from CGM to create glucose data reports to allow a PWD and their selected CP to identify glucose patterns and trends and has also been associated with greater quality of life when reports are viewed with a CP.[18] However, few older adults share their CGM data or review Clarity reports with a CP. Data from the WISDM trial showed that only 9.2% of older adults with T1D used data sharing, and only 32% used their smartphones to monitor their CGM data.[19] In our preliminary studies, older adults with diabetes reported an increased perceived need to have others monitor their glucose levels for safety purposes,[20] but few PWDs are adopting this technology.

The present intervention was designed to maximize the use of data sharing by PWDs and their CPs. Our prior work identified several barriers to using data sharing involving dyadic communication that involved patients' and partners' different expectations regarding family involvement.[20] PWDs frequently regarded diabetes as "their own illness" whereas spouses viewed the illness as more shared.[21,22] Improving collaboration and communication among those with type 2 diabetes[23] was associated with lower PWD and partner distress, higher satisfaction, and improved glycemic levels (among those with moderately elevated HbA1c).

The intervention is guided by the Dyadic Coping Model (see Figure 1),[24,25] a widely used framework for how individuals with chronic illness and CPs can be involved in chronic illness management. As applied to diabetes, dyadic coping involves two components: appraisal of the illness and coping efforts. Appraisal refers to whether the PWD and CP perceive diabetes as 'our' problem vs. 'my' or 'your' problem. Shared appraisal can initiate and facilitate coping strategies that are more collaborative to address diabetes stressors that are also perceived as shared.[26] When a PWD appraises diabetes as an illness that is shared with a CP, PWDs report more collaborative involvement from their spouse, greater relationship satisfaction, and less regimen distress.[22] Challenges can arise when one person in a dyad (e.g., the PWD) appraises diabetes as their own issue to deal with and the CP engages in high levels of involvement (e.g., wishes to be very involved in data sharing). That is, collaborative involvement of the CP may be detrimental when the PWD views diabetes as only their illness to deal with and does not consider its effects on the CP. The Dyadic Coping Model supports the value of a CP's collaborative involvement in a PWD's glucose monitoring via CGM.

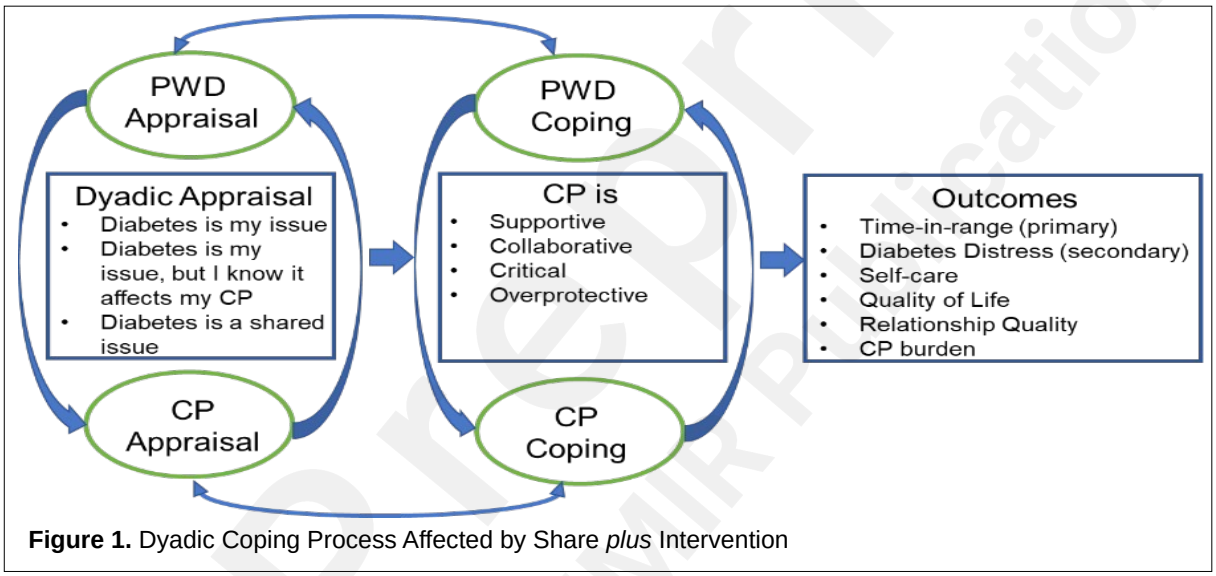

Figure 1. Dyadic Coping Process Affected by Share *plus* Intervention

The Share *plus* intervention framed by the Dyadic Coping Model begins with a discussion of how the PWD and CP appraise diabetes (e.g., patient's alone or shared with CP) and next communication regarding the preferred ways of involving the CP in data sharing (see Figure 1). For instance, the PWD is asked what words would be helpful and supportive from their CPs in response to a high or low glucose alarm and what might be viewed as critical or overprotective. Next, CPs are asked if this communication is acceptable to them and if they are willing to provide this requested support. In our preliminary studies, PWD who were initially hesitant to share their glucose data reported high satisfaction at 12 weeks.[27,28] These discussions facilitate an understanding of diabetes as a shared illness and the collaborative and supportive strategies that the CP can engage. Moreover, these discussions match data sharing strategies that fit with PWD appraisal of diabetes and are viewed as supportive rather than unsupportive. Such discussions will facilitate an action plan that will best align with the appraisal process of the PWD and CP.

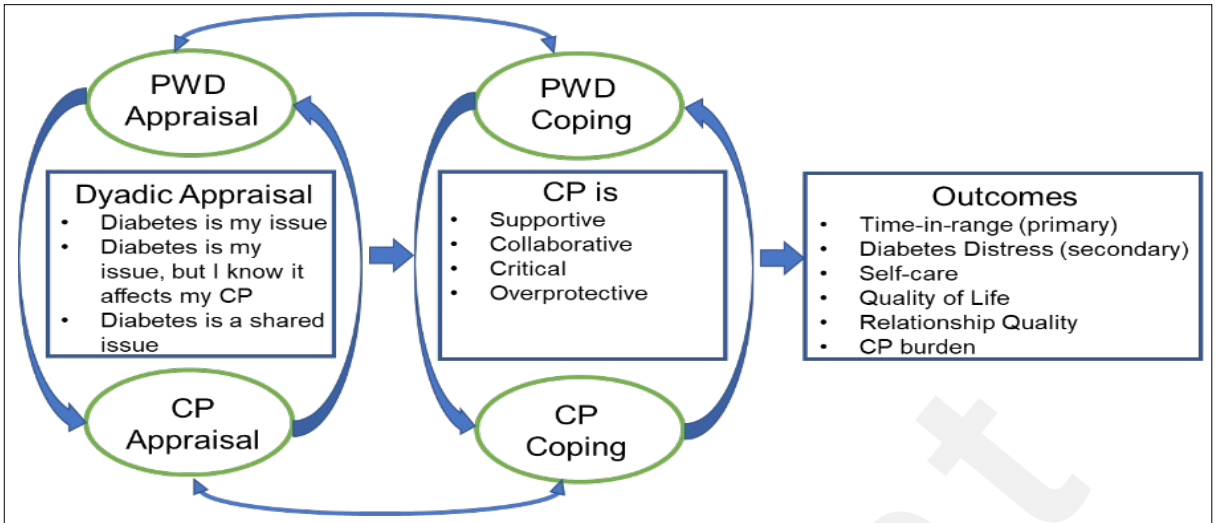

Figure 2. Dyadic Coping Process Affected by Share *plus* Intervention

Study Objectives

This study aims to:

1. Evaluate the feasibility, usability, and acceptability of the Share plus intervention compared to Follow+DSME.
2. Evaluate the effect of Share plus intervention on time-in-range (Primary Outcome) and diabetes distress (Secondary Outcome).
3. Explore differences between groups in PWD and CP dyadic appraisal and coping, quality of life (QoL), diabetes self-care, and CP burden at 12 and 24 weeks and associations of dyadic variables on outcomes.

Methods (e.g. with the subheadings "Recruitment", "Statistical Analysis", etc.)

Study Design This study will use a randomized 1:1 controlled trial to conduct a pilot test of 80 dyads to compare the Share plus intervention to the Follow plus diabetes self-management education intervention. The trial will include a 12-week active intervention to determine the change in primary (TIR) and secondary (diabetes distress) outcomes, followed by a 12-week observation-only phase to examine maintenance effects.

Setting

This clinical trial will be conducted in Utah and participants will be recruited at the state level and a national level using telehealth.

Sample and Recruitment

PWD and CPs will be recruited from three major healthcare systems in Utah in which we have identified champions who have assisted with recruitment in our preliminary studies (references). The University of Utah Enterprise Data Warehouse will be used to identify eligible PWD. An opt-out strategy will be employed using letters, postcards, emails, and text messages. Additionally, the Electronic Data Warehouse will be used to build a recruitment dashboard allowing the research team to reach out to contact high-volume providers to inform them of the study and to recruit participants in person before or after clinic visits.

Recruitment inside and outside of Utah will include 1) digital marketing strategies, and 2) diabetes clinician and provider networks. Digital marketing strategies include posting to type 1 diabetes social media groups. Professional groups, such as the Association of Diabetes Care and Education Specialists, will also be contacted to post information and digital flyers about the study.

Eligibility Criteria

PWD participants will be eligible if they are 1) ≥ 60 years old, 2) have a T1D diagnosis (may add more detail here), 3) currently using CGM, 4)HbA1c ≥ 7.5 and ≤ 11%, 5) able to read and write in either English or Spanish, 6) able to manage diabetes with respect to insulin administration and glucose monitoring (which may include assistance from a CP), and 6) naïve to using the Follow app and willing to use the Follow app. Participants with or without an insulin pump are eligible. Participants will be excluded if they have 1) a life expectancy estimated at < 1 year, 2) extreme visual or hearing impairment that would hinder the ability to use CGM, 3) stage 4 or 5 renal disease, 4) a history of psychiatric or psychosocial issues that could limit adherence to required study tasks or 5) a Montreal Cognitive Assessment score <19 indicating moderate to severe dementia.

Care Partner Care partner participants will be eligible if they 1) are identified by the PWD participant, 2) are ≥ 18 years old, 3) able to read and write in either English or Spanish, and 4) are willing to participate in a data sharing telehealth intervention study with the PWD participant. CPs will be excluded if they have a self-reported diagnosis of moderate or severe dementia or other medical conditions making it inappropriate or unsafe to fulfill the role of a CP. CPs will not be directly recruited.

Group Randomization

PWD (n=40) and CPs (n=40) who meet the study criteria and agree to participate will be asked to sign an informed consent with a digital signature. The PWD will be randomly assigned to one of two groups (40 dyads in the Share plus intervention group and 40 dyads in the Follow plus diabetes self-management education group) using a computer-generated schedule of randomly permuted blocks of sizes 2, 4, and 6 to minimize knowledge of the next participant's assignment. Group allocation will be executed in REDCap.

Share *plus* Intervention

The Share *plus* intervention will be delivered by Certified Diabetes Care and Education Specialists (CDCES) over three 60-minute sessions virtually using a HIPPA-compliant Zoom meeting platform with audio transcription with two additional dyad phone calls to reinforce the counseling sessions (Table 1). The three Share *plus* intervention sessions introduce new and increasingly advanced educational material and are designed to overcome PWD and CP reluctance in data sharing and to improve diabetes management. This includes training in dyadic CGM communication and problem-solving, leading to a data-sharing action plan.

Step 1. Shared Appraisal Assessment. Dyads are asked how they appraise diabetes with the following question: “When you think about diabetes, is it: 1) my issue to deal with as an individual, 2) my issue but I know it affects my CP, or 3) a shared issue.” The CPs are asked the same question, but “my” is substituted with “his/her.” A follow-up question will be asked, “Help me to understand why you selected this response.” If a PWD or CP views diabetes as their own, they are asked to consider something that was shared. The CDCES explores why it is shared and if it is easier to work on the problem together than alone. Next, PWDs and CPs are each asked about their confidence in sharing glucose data. Using scripted motivational interviewing questions, PWDs and their CPs are asked to discuss their answers. The objective of this discussion is to determine the initial comfort level with CGM data sharing within the dyad.

Step 2. Communication. Dyads are asked how comfortable they feel about data sharing. Examples are provided about how other PWDs have described the benefits of sharing their diabetes, such as an increased sense of teamwork, support, QoL, and decreased diabetes-related burden. The barriers to sharing glucose levels are also identified (e.g., glucose levels are private, and PWD does not want to be judged). The PWD next identifies effective and ineffective communication strategies around sharing hyper- and hypoglycemia. The PWD is asked 1) how they feel about their partner seeing their glucose levels and any

concerns they have about sharing their glucose data, 2) how they would like their CP to respond to their glucose numbers, and specifically what words or actions are viewed as supportive and helpful and what is unhelpful, nagging or controlling behavior, and 3) if or how they want their CP to help them to figure out the cause of a low or high glucose level. Education is provided about steps for clear communication. Finally, the CP is asked how they feel about this type of communication and if it is acceptable. The objective of this discussion is to explore supportive and unsupportive conversation strategies and foster their commitment to data sharing.

Step 3. Problem-solving. The dyad is asked to work together to set alarms on the PWD and CP smartphones (they can be set differently), the volume of alerts (e.g., can cause frustration), or use vibrate mode. First, CPs are asked to confirm their willingness to be a safety net for emergencies and look at alarms. The PWD is asked to acknowledge their willingness to look at their alarms. Next, dyads are coached to identify the expectations and length of waiting time before the CP should contact the PWD for a concerning glucose level and problem-solve an agreeable strategy for different alarms. For example, when a CP gets a low alarm with two arrows indicating a more rapidly decreasing glucose level, how long should they wait to contact the PWD, how long should they wait for a reply, if there is no reply, what action should they take? This discussion also includes the preferred mode by which the CP will contact the PWD (e.g., phone call, text, email, etc.). The dyad is also asked to discuss glucose trends once per week and then problem-solve if they will do this, when, and how. The objective of this third step is to guide the dyad in making and agreeing upon boundaries around data sharing.

Step 4. Action Planning. Dyads are asked to agree in writing how, when, and if they would like to be contacted for specific alarms as outlined in step 3. The type of communication that is identified as supportive responses to hyper- and hypoglycemia are recorded in the action plan from step 2. The action plan is documented and given to the dyad to set clear expectations around data sharing.

Step 5. Re-evaluating, Practicing, and Advancing. At weeks 4, and 8, dyads will review their experience using data sharing and discuss their concerns regarding communication, dyadic problem-solving around hypo- and hyperglycemia, and alarms, so that they can update their plan. Supplemental information is provided (as needed) on communication strategies (e.g., listening, reframing, being positive, and providing appreciative feedback). Dyads are asked to practice problem-solving skills related to their biggest identified problem in the previous weeks with data sharing. The Clarity app produces several reports, including an ambulatory glucose profile (AGP) that helps to determine glucose trends and patterns and can be downloaded on a computer or smartphone. The CDCES will have data-driven conversations from these reports at each session and, through shared decision-making, will develop a plan to help increase time in range (TIR) 70-180 mg/dl. In session two, the CDCES will instruct the dyad on how to use the Clarity app to download reports of glucose trends, how to review glucose patterns, and strategies to address hypo- or hyperglycemia patterns with a focus on food choices and healthy eating. Dyads will be instructed on setting up weekly automatic Clarity downloads and asked to set aside time to discuss these reports. In session three, the CDCES will review the Clarity download with a new focus on glucose pattern management with lifestyle changes (exercise, stress, sleep, illness). The action plan will be revised as needed at each session.

Handouts are provided at baseline to the dyads that support topics in each Share *plus* session. The format of the handouts includes education on topics such as hypoglycemia, CGM-specific actions to take to treat hypoglycemia, and tips for CPs on how to be

supportive when the PWD is experiencing hypoglycemia.

Table 1. Intervention and Control Group Activities

Week	Intervention Group- Virtual with Dyad Follow + Share *plus*	Control Group- Virtual with Dyad Follow + DSME
0	**Baseline** • CGM data collection for 14 days; no active intervention • Survey and home A1c kit completion • Set up Clarity to allow access to data	**Baseline** • CGM data collection for 14 days; no active intervention • Survey and home A1c kit completion • Set up Clarity to allow access to data
2	**Start Share *plus* Intervention** • Set up Follow app • Start Share *plus* intervention • Communication and problem-solving strategies • Detailed action plan including glucose targets	**Start usual care** • Set up Follow app • Two education handouts provided covering ADCES7 self-care education topics: Monitoring and Taking Medication
3	**Dyadic Phone call:** Reinforce Share *plus* intervention and provide technology support	
4	**Share *plus* Intervention + glucose pattern management with focus on food choices and healthy eating** • Review communication and problems • New communication content • Revise action plan as needed for communication and problem-solving hypo- and hyperglycemia, • Dyadic glucose pattern management training using Clarity, set automatic Clarity downloads • Dyad set goals for regular times to discuss glucose trends and problem-solving,	**Usual care intervention** • Review goals and progress • Two education handouts provided on ADCES7 topics: Reducing Risks and Health Eating
6	**Dyadic Phone call:** Reinforce Share *plus* intervention and provide technology support	
8	**Share *plus* Intervention + glucose pattern management with lifestyle (exercise, stress, illness, etc.)** • Review communication and problems • Dyadic glucose pattern management using Clarity • Dyadic review of glucose targets after an in-depth analysis of CGM data and dyadic treatment strategies to improve glucose TIR	**Usual care interventions** • Review goals and progress • 3 education handouts ADCES7 handouts on Being Active, Problem Solving, Healthy Coping
12	**Data Collection- End of Active Intervention** • Measures and home A1c kit completion, • Retrieve TIR data from Clarity	**Data Collection- End of Active Intervention** • Measures and home A1 kit completion • Retrieve TIR data from Clarity
24	**Data Collection- End of Observation Phase** • Measures, home A1c kit completion, Clarity download	**Data Collection- End of Observation Phase** • Measures, home A1c kit completion, Clarity download

Follow plus DSME Intervention

Dyads in the Follow plus DSME Intervention will receive 3 diabetes education sessions (Table 1.). The CDCES will cover topics from the Association of Diabetes Care and Education Specialists (ADCES7*)* educational curriculum including healthy coping, healthy eating, being active, taking medication, reducing risks, and problem-solving in three sessions. ADCES handouts are provided at baseline on the ADCES7 educational topics.

Outcomes and Measures

Feasibility, usability, and acceptability measures will be collected throughout the study, both quantitatively and qualitatively. Feasibility for this study is operationalized to include: the ability to recruit the target population, retention of participants, participant adherence to the study protocol, CDCES fidelity in delivering the intervention, and the intervention dose provided. Usability includes measures of processes to complete the intervention and a measure used to examine the reliability and validity of the telehealth and SHARE *plus* technology intervention. Acceptability will include PWD and CP satisfaction with the Share *plus* intervention.

The three Share *plus* sessions will be conducted on HIPPA-compliant Zoom and recorded and transcribed using the meeting transcription feature. Dyadic data will be collected

qualitatively in our intervention feasibility data and quantitatively. The qualitative feasibility intervention data includes collaborative involvement, cooperative actions, challenges, supportive/critical communication, problem-solving discussions re: hyper- and hypoglycemia, solutions discussed then implemented, unsuccessful and successful solutions, and barriers to protocol completion. Quantitative measures usability measures include process measures such as appointment attendance, length of all sessions, number of unscheduled appointments for extra assistance, and number of telephone calls for PWD and CP support. Engagement data includes PWD and CP's reported frequency of viewing glucose data, responding to alarms, and intent to continue using the Follow app. Other quantitative measures will be available at baseline, 12 and 24 weeks, and include interpersonal processes such as diabetes appraisal,[22] social support,[29] relationship quality (ref),[30] diabetes self-care,[31] care partner burden,[32] quality of life[33], and percent of protocol completion. The primary outcomes are TIR and diabetes distress[34] and partner diabetes distress.[35] CGM data will be collected from the Clarity reports for 14 days at each time point (Clarity website stores data continuously). Other descriptive measures include glycemic metrics from CGM data.[36]

Data Management and Ethics Approval

All data will be entered into the REDCap database, with data storage on a secure, dedicated research server. CGM data will be collected from the Clarity reports for 14 days at each baseline, 3 and 6 months. All individuals involved in screening and data entry will be trained to use the database. The research team and the PI will review entered data for completeness and accuracy. The study procedures were approved by the University of Utah Institutional Review Board (00160673)

Statistical Methods and Analysis

Study Aim 1 Analysis

Quantitative feasibility, acceptability, and usability data will be described using frequencies and percentages. Acceptability will be summarized based on Likert questions and open-ended questions. Usability will be examined separately for the intervention and control groups based on the System Usability Scale[37], with a study benchmark of 80% or more of participants having a score of ≥ 68 indicating good usability. The qualitative data from intervention transcripts will be checked for transcription accuracy. Next, feasibility data will be qualitatively coded, line-by-line, using principles of qualitative thematic analysis.[38,39] Codes from a codebook will be compared, contrasted, and collapsed to develop corresponding themes.[40-42]

Study Aim 2 Analysis

Our *primary research question* asks if % TIR (70-180 mg/dl) will be significantly higher in the Share *plus* versus the control group. TIR will be computed based on two weeks' worth of data at baseline (prior to intervention), and 2 weeks each post-intervention (week 12), and at follow-up (week 24). Primary efficacy evaluation expectation would show no difference for % TIR at baseline but improvement in the Share+ condition at 12 weeks in comparison to the control. Further, improvement at 24 weeks in comparison to control would be suggestive of a maintained benefit. We will assess the efficacy of our intervention for % TIR using a multilevel model with a random intercept. Time will be captured through two dummy codes treating the baseline as the referent. The significance and direction of the first dummy code captures change from baseline to 12 weeks. The significance and direction of the second dummy code captures change from baseline to 24 weeks. Condition will then moderate these effects as a means to determine the efficacy. -Follow-up analyses will compare 12 weeks to 24 weeks if some efficacy is still found at 24 weeks in comparison

with baseline. Exploratory analyses will include examining age, duration of T1D, education level, and number of complications as covariates. In all cases, mean differences along with 95% confidence intervals will be reported. All tests will be evaluated using an α =.05 two-tailed.

Study Aim 3 Analysis

Our exploratory question asks what differences in PWD and CP dyadic appraisal and coping, QoL, diabetes self-care, and CP burden, will be found between the Share *plus* intervention versus the control group. We will explore differences between the groups on these measures analogous multilevel models as in Study Aim 2 separately for PWDs and CPs. Exploratory evaluation will be performed through a between-by-within interaction with the expectation of there being no difference for measures at baseline but significant differences between the two conditions at 12 and 24 weeks. For the second half of the Aim, we will explore questions like, "Does improvement in self-care behaviors and dyadic relationship quality lead to improvements in PWD TIR?" In this case, we will utilize regression models with PWD TIR at 24 weeks regressed on baseline TIR and difference change score of self-care at 12 weeks minus baseline. Interaction terms with treatment will be included to look at the impact of the intervention on these associations. While we recognize that the study is underpowered for formal analysis, these preliminary trends can inform future fully powered dyadic and mediation analyses to determine the underlying processes that are influenced by the intervention.

Power and Sample Size

Power analyses were conducted in GPower 3.1 based on population-level values. It will parallel the results of a Monte Carlo Study as long as there is minimal missing data and assumptions (e.g., normality) are met. We deemed these acceptable assumptions for the proposed study. Power calculations were based on the F statistic from within by between mixed design repeated measures ANOVA. We stipulated an n=80, power=.80, and alpha=.05 with three repeated measures time points and two between-level groups. This parallels aims 2 and 3, examining for an intervention by time interaction such that no difference is expected at baseline, but a difference should be detectable at 12 and 24 weeks. The sample size allows us to detect an f of 0.15 which corresponds to a d=.3 which falls into the small to moderate effect size range following Cohen's suggested benchmarks. This would be sufficient given that we wished to detect a minimally important difference (MID) of ≥5% improvement in TIR, which with a SD of 20% corresponds to Cohen's d of .25. Detecting a smaller effect size even with a larger sample size would not have as much clinical utility. Analyses and power calculations are similar for the diabetes distress scale. With a clinically meaningful change of 0.5 points and a SD of 1.5-2.0, this corresponds to a d=.25 to d=.3. Therefore, the power to detect a d=.3 as described above for TIR will also be sufficient to detect a meaningful change in the distress scale. For both sample size calculations, there is minimal loss in effect size detection with losing as much as 20% of the expected sample size. This implies that we should be fairly robust to power loss due to attrition, technical issues, or other reasons for expecting incomplete data, though data loss should be fairly minimal for TIR, with the common occurrence being technical issues that might lead to 2-3 of the days lost for calculating % out of range. Of note, given that we will utilize BLIMP to impute missing data this therefore provides a conservative estimate of power and sample size.

Missing Data

The proposed analyses will be based on all available observations in combination with multiple imputations to avoid distorting variance or inducing bias.[43] We operationalize adherence as the mean hours that CGM is worn per day. The CGM r package iglu[44,45]

utilizes linear interpolation for customizable small windows of missing data (for example 20 minutes) within the hours specified. For longer periods of missing data beyond 20 minutes, the data will not be interpolated by iglu as this may bias results, based on current recommendations for CGM.[46] Instead, we will utilize the BLIMP program which can generate a fully conditional multiple imputation solution for multilevel data structures.[46] Little's MCAR test will be utilized to identify necessary imputation predictors. This methodology should be efficient for both missing at random and missing completely at random circumstances. Missing data patterns will be examined and discussed by the team experts to consider if any may be suggestive of non-random missingness. Similar procedures will be applied to the validated behavioral measures.

Data Monitoring

Our team has developed a study operations manual and an intervention manual building on the manuals developed in our feasibility studies.[27,28,47,48] These manuals are used to ensure maximum compliance and protection with good clinical practices for research and include processes such as recruitment, informed consent, and protection of personal health information and video data. Participants complete electronic surveys using a weblink to REDCap (Research Electronic Data Capture), a HIPAA-compliant web-based application hosted at the University of Utah Center for Clinical and Translational Science Institute, which securely stores and protects data. No names appear on any surveys and will only be used by the study team. The qualitative data collected from the Zoom educational sessions will be entered into REDCap by trained research assistants. This data is backed up continuously and protected by the University of Utah computer security systems.

CGM data is collected from Clarity[17] reports for 14 days at each time point and is stored in REDCap. CDCES access Clarity reports at each Share *plus* intervention session to provide dyadic coaching.

A1c data is being collected using A1c test kits, which require 1 drop of blood (similar to checking a glucose level).[49] Participants mail the A1c kits directly to the laboratory which is traced with a tracking number to ensure privacy. This process will allow the study team to link the data to the participant once the A1c has been processed.

Harms The risk of harm to participants, PWD, and their CP's, is minimal. However, we have protocols in place if a participant is harmed. These protocols include reporting events to the institutional review boards and our data safety monitoring board in accordance with institutional and federal policies.

Results

We began recruiting participants on 11/2/2023. We expect to conclude this study in March 2026.

Discussion

Principal Results

The Share *plus* intervention examines dyadic support for using CGM with data sharing in older adults with T1D. The clinical promise of CP data sharing to improve diabetes management and glycemic levels and, thus, reduce complications will be greatly enhanced through an intervention that removes barriers and strengthens dyadic communication and support for the growing number of older adults with diabetes. In this randomized controlled trial, we will evaluate feasibility and acceptability. The expected outcome is that the Share *plus* intervention will have a clinically significant intervention signal (increased time-in-range and lower diabetes distress) indicating readiness for a fully powered trial. By leveraging the full potential of technology and CP interventions, we may optimize the support that CPs can

provide for effective glucose management in older adults with T1D.

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Authorship: NA, ML, CB conceived the study. EI, JB, BG were involved in protocol development and implementation. NA, ML, CB wrote the manuscript. All authors reviewed, edited, and approved the final manuscript for publication.
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Guarantor Statement: Dr. Nancy A. Allen is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Abbreviations

CGM=Continuous Glucose Monitor
T1d=Type 1 Diabetes
PWD= Persons with diabetes
DSMES=Diabetes Self-Management Education and Support
CP=Care Partner
TIR=Time-in-range
QoL=Quality of Life
CDCES=Certified Diabetes Care and Education Specialists
AGP=Ambulatory Glucose Profile
ADCES7=Association of Diabetes Care and Education Specialists Educational Curriculum
MID=Minimally Important Difference

References:

1. Center for Disease Control and Prevention. National Diabetes Statistics Report. https://www.cdc.gov/diabetes/data/statistics-report/index.html. Published 2024. Accessed March 23, 2024.
2. Lipska KJ, Ross JS, Wang Y, et al. National trends in US hospital admissions for hyperglycemia and hypoglycemia among Medicare beneficiaries, 1999 to 2011. *JAMA internal medicine*. 2014;174(7):1116-1124.
3. Schütt M, Fach EM, Seufert J, et al. Multiple complications and frequent severe hypoglycaemia in 'elderly' and 'old' patients with Type 1 diabetes. *Diabetic medicine : a journal of the British Diabetic Association*. 2012;29(8):e176-179.
4. Sircar M, Bhatia A, Munshi M. Review of Hypoglycemia in the Older Adult: Clinical Implications and Management. *Can J Diabetes*. 2016;40(1):66-72.
5. Zupa MF, Lee A, Piette JD, et al. Impact of a Dyadic Intervention on Family Supporter Involvement in Helping Adults Manage Type 2 Diabetes. *J Gen Intern Med*. 2021:1-8.
6. Silliman RA, Bhatti S, Khan A, Dukes KA, Sullivan LM. The care of older persons with diabetes mellitus: families and primary care physicians. *Journal of the American Geriatrics Society*. 1996;44(11):1314-1321.
7. Nicklett EJ, Heisler ME, Spencer MS, Rosland AM. Direct social support and long-term health among middle-aged and older adults with type 2 diabetes mellitus. *J Gerontol B Psychol Sci Soc Sci*. 2013;68(6):933-943.
8. Rodakowski J, Rocco PB, Ortiz M, et al. Caregiver Integration During Discharge Planning for Older Adults to Reduce Resource Use: A Metaanalysis. *Journal of the American Geriatrics Society*. 2017;65(8):1748-1755.
9. Lee AA, Piette JD, Heisler M, Rosland AM. Diabetes Distress and Glycemic Control: The Buffering Effect of Autonomy Support From Important Family Members and Friends. *Diabetes care*. 2018;41(6):1157-1163.
10. Dexcom. Continuous Glucose Monitoring with G6: How it works. https://www.dexcom.com/continuous-glucose-monitoring?utm_source=adwords&utm_campaign=b&sfc=701f3000000athzAAA&gclid=CjwKCAiAlO7uBRANEiwA_vXQ-17k2k3GiUf8wyUZC-WKnqlyFY5q2lircPCtg6IePmvSW3vW2i27cxoCMw8QAvD_BwE. Published 2019. Accessed November 25, 2019.
11. American Diabetes Association Professional Practice Committee. 13. Older adults: Standards of Care in Diabetes-202*Diabetes Care*. 2024;47:S244-257.
12. Agiostratidou G, Anhalt H, Ball D, et al. Standardizing Clinically Meaningful Outcome Measures Beyond HbA(1c) for Type 1 Diabetes: A Consensus Report of the American Association of Clinical Endocrinologists, the American Association of Diabetes Educators, the American Diabetes Association, the Endocrine Society, JDRF International, The Leona M. and Harry B. Helmsley Charitable Trust, the Pediatric Endocrine Society, and the T1D Exchange. *Diabetes care*. 2017;40(12):1622-1630.
13. Need for Regulatory Change to Incorporate Beyond A1C Glycemic Metrics. *Diabetes care*. 2018;41(6):e92-e94.
14. Dexcom. Video on remote viewing of CGM data through the Dexcom Share feature. https://provider.dexcom.com/education-research/cgm-education-use/videos/setting-dexcom-share-and-follow#:~:text=The%20built%2Din%20Dexcom%20Share,user's%20glucose%20in%20real%20time. Published 2020. Accessed September 7, 2020.
15. Derdzinski M. Utilization of Dexcom G6 Features by Age. Paper presented at: Advance

Technology and Treatments in Diabetes2020; Madrid Spain.
16. Dexcom. Dexcom Follow App for Friends and Family. https://www.dexcom.com/dexcom-follow. Published 2022. Accessed June 25, 2022.
17. Dexcom Inc. Dexcom Clarity User Guide. In: Dexcom Inc; 2020:1-97.
18. Polonsky WH, Soriano EC, Fortmann AL. The Role of Retrospective Data Review in the Personal Use of Real-Time Continuous Glucose Monitoring: Perceived Impact on Quality of Life and Health Outcomes. *Diabetes technology & therapeutics*. 2022.
19. Pratley RE, Kanapka LG, Rickels MR, et al. Effect of Continuous Glucose Monitoring on Hypoglycemia in Older Adults With Type 1 Diabetes: A Randomized Clinical Trial. *Jama*. 2020;323(23):2397-2406.
20. Allen NA, Litchman ML, Chamberlain J, Grigorian EG, Iacob E, Berg CA. Continuous Glucose Monitoring Data Sharing in Older Adults With Type 1 Diabetes: Pilot Intervention Study. *JMIR Diabetes*. 2022;7(1):e35687.
21. Berg CA, Helgeson VS, Tracy EL, et al. Daily illness appraisal and collaboration in couples with type 1 diabetes. *Health psychology : official journal of the Division of Health Psychology, American Psychological Association*. 2020;39(8):689-699.
22. Helgeson VS, Berg CA, Kelly CS, et al. Patient and partner illness appraisals and health among adults with type 1 diabetes. *Journal of behavioral medicine*. 2019;42(3):480-492.
23. Trief PM, Fisher L, Sandberg J, Hessler DM, Cibula DA, Weinstock RS. Two for one? Effects of a couples intervention on partners of persons with Type 2 diabetes: a randomized controlled trial. *Diabetic medicine : a journal of the British Diabetic Association*. 2019;36(4):473-481.
24. Berg CA, Upchurch R. A developmental-contextual model of couples coping with chronic illness across the adult life span. *Psychological bulletin*. 2007;133(6):920-954.
25. Bodenmann G. Dyadic coping: A systemic-transactional view of stress and coping among couples: Theory and empirical findings. *European Review of Applied Psychology / Revue Européenne de Psychologie Appliquée*. 1997;47(2):137-141.
26. Zajdel M, Helgeson VS, Butner JE, Tracy EL, Berg CA. A multimethod approach to measuring communal coping in adults with type 1 diabetes. *Health psychology : official journal of the Division of Health Psychology, American Psychological Association*. 2022;41(1):23-31.
27. Allen NA, Bristol AB, Grigorian EG, Iacob E, Berg CA, Litchman ML. SHARE plus: Delivering a Telehealth CGM Data-Sharing Intervention to Older Adults and Their Care Partners. *Diabetes Spectrum*. 2021;35(1):16-25.
28. Allen NA, Litchman ML, Chamberlain J, Grigorian E, Berg C. Continuous Glucose Monitoring Data Sharing in Older Adults with Type 1 Diabetes: A pilot intervention study. *JMIR Diabetes* 2021;16(1).
29. Berg CA, Schindler I, Smith TW, Skinner M, Beveridge RM. Perceptions of the cognitive compensation and interpersonal enjoyment functions of collaboration among middle-aged and older married couples. *Psychology and aging*. 2011;26(1):167-173.
30. Pierce GR, Sarason IG, Sarason BR. General and relationship-based perceptions of social support: are two constructs better than one? *J Pers Soc Psychol*. 1991;61(6):1028-1039.
31. Weinger K, Butler HA, Welch GW, La Greca AM. Measuring diabetes self-care: a psychometric analysis of the Self-Care Inventory-Revised with adults. *Diabetes care*. 2005;28(6):1346-1352.
32. Kovacs Burns K, Nicolucci A, Holt RI, et al. Diabetes Attitudes, Wishes and Needs second study (DAWN2™): cross-national benchmarking indicators for family members living with people with diabetes. *Diabetic medicine : a journal of the British Diabetic Association*. 2013;30(7):778-788.

33. Hajos TR, Pouwer F, Skovlund SE, et al. Psychometric and screening properties of the WHO-5 well-being index in adult outpatients with Type 1 or Type 2 diabetes mellitus. *Diabetic medicine : a journal of the British Diabetic Association*. 2013;30(2):e63-69.
34. Fisher L, Polonsky WH, Hessler DM, et al. Understanding the sources of diabetes distress in adults with type 1 diabetes. *Journal of diabetes and its complications*. 2015;29(4):572-577.
35. Polonsky WH, Fisher L, Hessler D, Johnson N. Emotional Distress in the Partners of Type 1 Diabetes Adults: Worries About Hypoglycemia and Other Key Concerns. *Diabetes technology & therapeutics*. 2016;18(5):292-297.
36. Battelino T, Danne T, Bergenstal RM, et al. Clinical Targets for Continuous Glucose Monitoring Data Interpretation: Recommendations From the International Consensus on Time in Range. *Diabetes care*. 2019;42(8):1593-1603.
37. Brooke J. SUS-A quick and dirty usability scale. *Usability evaluation in industry*. 1996;189(194):4-7.
38. Morgan DL. Qualitative content analysis: a guide to paths not taken. *Qualitative health research*. 1993;3(1):112-121.
39. Sandelowski M. Whatever happened to qualitative description? *Research in nursing & health*. 2000;23(4):334-340.
40. Tesch R. *Qualitative research: Analysis types and software tools*. Psychology Press; 1990.
41. Huberman AMS, Johnny. *Qualitative data analysis: a methods sourcebook*. Third edition ed. Thousand Oaks, California: SAGE Publications, Inc.; 2014.
42. Tesch R. *Qualitative research: Analysis types and software*. Routledge; 2013.
43. Donaldson GW, Moinpour CM. Learning to live with missing quality-of-life data in advanced-stage disease trials. *J Clin Oncol*. 2005;23(30):7380-7384.
44. Broll S, Urbanek J, Buchanan D, et al. Interpreting blood glucose data with R package iglu. *PLoS one*. 2021;16(4).
45. Chun E, Broll S, Buchanan D, et al. iglu: Interpreting Glucose Data from Continuous Glucose Monitors. In:2023.
46. Olsen MT, Klarskov CK, Dungu AM, Hansen KB, Pedersen-Bjergaard U, Kristensen PL. Statistical Packages and Algorithms for the Analysis of Continuous Glucose Monitoring Data: A Systematic Review. *Journal of diabetes science and technology*. 2024:19322968231221803.
47. Allen NA, Grigorian EG, Iacob E, Mansfield K, Berg CA, Litchman ML. CGM Data Sharing in Older Adults: A Qualitative Study. *The Science of Diabetes Self-management and Care* 2021;47(4).
48. Allen NA, Grigorian EG, Mansfield K, Berg CA, Litchman ML. Continuous glucose monitoring with data sharing in older adults: A qualitative study. *Journal of clinical nursing*. 2023;32(19-20):7483-7494.
49. Jacobsen LM, Bocchino LE, Lum JW, et al. Accuracy of Three Commercial Home-Use Hemoglobin A1c Tests. *Diabetes technology & therapeutics*. 2022;24(11):789-796.

Supplementary Files

Figures

Dyadic Coping Process Affected by Share plus Intervention.