TBM

BRIEF REPORT

# Pivoting during a pandemic: lessons learned from transitioning a multisite randomized controlled trial to a remote protocol in response to COVID-19

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## Abstract

THR1VE! is an ongoing multisite randomized clinical trial of a positive psychology intervention designed to treat diabetes distress and improve glycemic outcomes in teens with type 1 diabetes. Due to the COVID-19 pandemic restrictions on clinical research and changes in diabetes clinical care, THR1VE! was adapted from an in-person enrollment protocol to a remote protocol through a series of development and testing strategies. We discuss the process of transitioning the protocol and the demonstrated feasibility of ongoing recruitment, enrollment, and retention outcomes. These findings offer support for a remotely transitioned protocol that has larger applications for ongoing and future clinical research.

## Keywords

Type 1 diabetes, Remote protocol, COVID-19, Protocol, Clinical trial

**Implications**

**Implications for Researchers**: We identified strategies to engage a representative sample and replicate in-person enrollment protocols to adhere to COVID-19-related restrictions.

**Implications for Policy Makers**: Additional resources may be needed for researchers to engage representative samples of participants in behavioral trials and disseminate interventions to larger populations.

**Implications for Practice**: Some of the strategies developed for the remote enrollment protocol, such as screen sharing and remote access, could be used to engage with patients in telehealth visits.

## INTRODUCTION

Type 1 diabetes (T1D) is the third most common chronic illness in individuals under the age of 20, affecting 1 in every 433 children, with the peak age of onset in adolescence [1]. Diabetes management requires frequent monitoring of blood glucose levels, careful attention to carbohydrate intake, and adjustments to insulin doses related to diet and physical activity. Even with new diabetes technology, such as continuous glucose monitors (CGMs), managing T1D remains demanding, and most adolescents have trouble consistently following all of the recommendations for daily management. In fact, only 17% of teens in a national sample met the recommended target for glycemic control (HbA1c < 7.5%) [2].

Diabetes distress, or emotional distress related to the burden of living with diabetes, is strongly associated with problems with diabetes management and poorer glycemic control. Approximately half of all adolescents with T1D experience clinically significant diabetes distress and will remain distressed without intervention [3]. THR1VE! is a positive psychology intervention aimed at treating diabetes distress and improving glycemic outcomes in teens ages 13–17 with T1D [4] (NCT03845465). Based on the Broaden-and-Build-Theory, which posits that greater positive affect enhances the use of adaptive coping strategies, this intervention induces positive affect (e.g., feeling happy, cheerful, proud) to help adolescents manage diabetes-related stress [5, 6]. This ongoing trial will include 200 teens with T1D and their parents to evaluate the automated text-messaging intervention.

In this paper, we describe the process of transitioning a multisite randomized controlled trial protocol to a remote protocol in response to the COVID-19 pandemic and changes in pediatric diabetes clinical care. First, we describe the development and testing of the remote protocol. We then examine the feasibility of ongoing recruitment, enrollment, and participant retention outcomes of the remote protocol as compared to the in-person recruitment and enrollment protocol. These findings have a larger application to current and future clinical research, as the use of remote technologies and services are expected to accelerate within clinical trials during and following the COVID-19 pandemic, based on patient preference for telehealth visits [7].



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## METHODS

### Recruitment (in-person)

Prior to COVID-19 restrictions, research assistants (RAs) at two sites (both academic medical centers with large pediatric diabetes clinics) approached families at their regularly scheduled diabetes clinic appointments to describe the THR1VE! study. Adolescents are eligible to participate if they (a) are between the ages of 13–17; (b) have been diagnosed with T1D for at least 12 months; (c) report at least moderate diabetes distress; (d) speak and read English; and (e) have access to a phone that can send/receive text messages. Potentially eligible families were identified from the electronic clinic schedule using preliminary inclusion and exclusion criteria (age, date of diagnosis). Families who were interested in participating after hearing the study summary were then asked to provide verbal consent (from the parent and assent from the teen) for the teen to complete a short screening survey, to determine if they had consistent access to a cellphone with texting capabilities and to assess their level of diabetes distress with the Problem Areas in Diabetes-Teen (PAID-T) [8]. The screening survey was administered on a tablet using the electronic data collection web application, REDCap. Families that screened eligible were invited to stay after their clinic appointment to enroll in the study.

### Enrollment (in-person)

The enrollment activities took place in a private room where the teen and parent completed eConsent forms and baseline surveys in REDCap, administered via tablets, including information about diabetes device use. Parent and teen dyads were then randomized into the Diabetes Education + Positive Affect (PA) group or the Diabetes Education group (details about the methods and procedures of the intervention are described in the protocol paper, written prior to the COVID-19 pandemic [4]). All teens, regardless of group assignment, completed a Health Behavior Contract committing to a positive change in behavior related to their current diabetes management, with guidance from an RA. All teens also received a 12-page packet of diabetes educational materials based on publicly available recommendations from the ADA (www.diabetes.org) and other resources.

Teens randomized to the PA group spent an additional 5–10 min working one-on-one with an RA to complete the Positive Affect Interview. The RA guided the teen through activities that highlighted the teen's important values to encourage self-affirmation (e.g., being creative, relationship with family), and moments of gratitude in their everyday life. Responses from this worksheet were entered into the REDCap database so that the teen received tailored text messages during the active phase of the intervention (8 weeks). The RA also met with parents in the PA group to provide instructions on giving positive affirmation to their teens at least once per week for the duration of active intervention.

At the end of enrollment activities, teens were given a study folder including their worksheet activities (PA group), educational packet, and health behavior contract (all teens). As compensation for their time, participants received Amazon gift cards, along with small retention items (pen and a T-shirt with the study logo). Finally, the parent and teen signed receipts for the gift cards.

### Engagement (in-person)

RAs administered follow-up surveys on REDCap via tablets to teens and parents in the clinic waiting room when they came in for their regularly scheduled 3-, 6-, and 12-month clinic appointments. Clinical data (HbA1c and blood glucose data) were extracted from the medical chart for the corresponding clinic visit. As compensation, participants received Amazon gift cards, along with additional small retention items at each time point.

### Transition to remote recruitment

Due to the COVID-19 pandemic and social distancing requirements, our research team stopped in-person recruitment and enrollment on March 12, 2020. At this point in the study, 21 adolescent-parent dyads had been enrolled in the study (14 from site A and 7 from site B). The team prioritized collecting follow-up data from enrolled participants, added COVID-19 related questions to surveys at all time points, and procured mail-in hemoglobin A1c (HbA1c) kits to replace point-of-care HbA1c values that were not obtained when participants had telehealth appointments with their diabetes providers. A group of pediatric psychologists developed COVID-19 questionnaires for both the teen and parent focused on the impact of COVID-19 on the teen's diabetes management, the impact of COVID-19 on the teen's and parent's mood and daily routines, and any major life changes that took place as a result of COVID-19 (e.g., loss of job, new school). This information will be used to analyze how the pandemic has affected the health behaviors of our participants and to interpret how the experience of COVID-19 may affect our primary data.

These changes were approved by the IRB in late April 2020. The development of a remote protocol began in May 2020 to continue recruiting and enrolling families without being physically in the clinic. The necessary materials were adapted, and the remote protocol was developed by early June 2020 using remote technologies including phone calls and Zoom. Each site tested and refined the protocol amongst study personnel, and remote recruitment began at the end of June 2020.

### Recruitment (remote)

Recruitment procedures transitioned from in-person approaches to remote outreach via phone and mail. The original recruitment script was adapted to a phone script used to call potential participants at home within 1 week of their telehealth appointment. Site B also began sending letters to potential participants notifying them of our plans to contact their family and giving them the opportunity to opt-out of calls, in line with other trial protocols at this site. Recruitment calls are attempted around the time of day when teens are most likely to be available. In the summer, the optimal time to call was after noon, due to variability in the teens' daily schedule and sleep patterns, and in the fall/winter, optimal times have been after noon, after (virtual or in-person) school. Calls are made to the parent's home phone number or cellphone number listed in the medical record. If the call goes unanswered, the RA leaves a voicemail and attempts to contact them two additional times. If three phone call attempts are left unanswered, the family is approached again in 3 months. If the call is answered, the RA explains the study, similar to in-person recruitment. If teens are available, they are invited to join the call to hear about the study. If teens are not available, the RA asks for the parent's permission to contact the teen separately. If the family agrees to participate in the screening process, a link to the eligibility survey is sent to the teen through email or text message to complete on their device. The RA stays on the phone as the teen completes the survey to answer clarifying questions and share the results of the survey upon completion. If the teen screens eligible, the RA then schedules the remote enrollment appointment within the 2-week eligibility window.

### Enrollment (remote)

Enrollment procedures were also adapted for remote administration. We chose to use the Zoom platform for the baseline study visit. Given the widespread use of Zoom during the pandemic in both school and workplace settings, families were likely to be familiar with the functionality. In addition, this technology is compatible with many devices and is available for limited purposes at no cost, making it accessible to many families. RAs use telehealth-compliant versions of Zoom, available through their research institutions, which allows us to maintain high security and confidentiality for the participant families.

On the day of the enrollment, the RA texts the teen and parent an hour before their enrollment begins to confirm. When the participants join the Zoom call to begin enrollment, the RA describes the process of troubleshooting technology if either party were to experience difficulties (i.e., RA will call back). The RA then begins the enrollment by describing the THR1VE! study in detail, and the consent and assent forms are opened in REDCap on the participant-facing version and sent digitally to each teen and parent via text or email. The teen and parent then open their materials on separate personal devices to complete their consent/assent form and baseline surveys. After completing baseline surveys, the dyads are randomized to either the Diabetes Education or the PA group using the REDCap randomization functionality, which draws from an algorithm developed by the biostatistician for the project. The RA opens PDF versions of enrollment materials (i.e., The Health Behavior Contract, the educational packet, and Positive Affect Interview worksheets) and shares the view of their screen with the families using the Zoom "Screen Sharing" function, which is available on all types of devices. In addition to screen sharing, the RA utilizes the "Screen Control" function of Zoom, available to participants using a device with a mouse/trackpad and keyboard. Screen control can be activated and deactivated at any time, allowing guided use of screen control abilities by participants at appropriate times (e.g., filling in an example of gratitude). For lower-income families who may not have access to devices with mouse/trackpad technology, the RA alternatively screen shares the materials with the family and prompts verbal responses from the participants, and types their responses in real-time. We designed the remote enrollment protocol to be as engaging as the in-person enrollment, and the utilization of Zoom functionality promotes participant interaction with the digital materials.

### Engagement (remote)

After completing the enrollment, the Health Behavior Contract, the education packet, and PA group worksheets are printed and mailed to the participants' homes (Fig. 1). Participants are also emailed a digital copy of the materials. This emulates receiving physical copies of enrollment materials after in-person enrollments. Within a week of enrollment, families are also mailed baseline retention items (e.g., T-shirt and pen with study logo). If the teen received clinical care through telehealth and therefore does not have a point-of-care or outside laboratory HbA1c value in the medical record, they are mailed an at-home HbA1c kit (Fig. 1). The kit is completed by the teen and returned directly to a central laboratory. The laboratory reports the HbA1c value to the study team, and a member of the study team informs the parents that an HbA1c value is available. If the family wants to know the value, it is reported to the parent over the phone by an RA, to avoid sharing protected health information by email.

Since we are not able to meet most participants in the diabetes clinic to complete follow-up surveys, parent and teen surveys are sent digitally via email or text at the onset of 3-, 6-, and 12-month follow-up

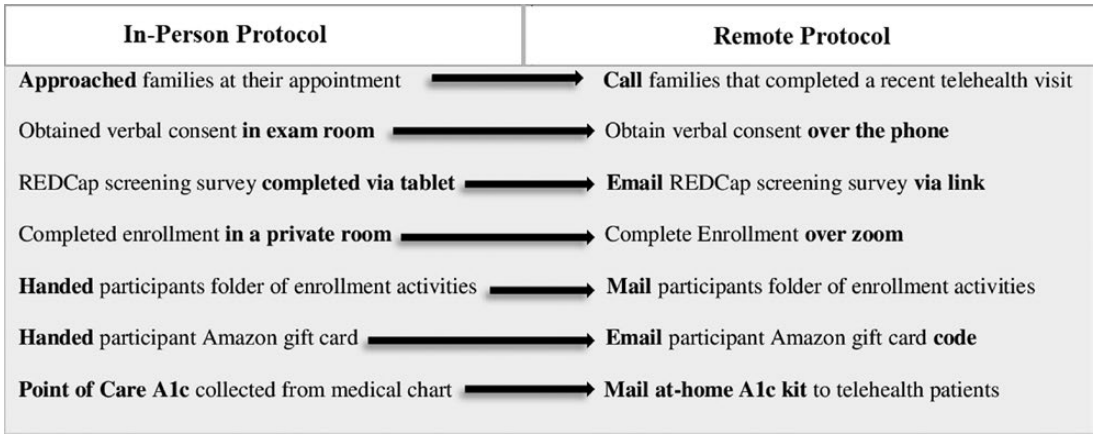


**Fig 1**| Changes from in-person to remote protocols.

periods or on the date of their diabetes clinic appointment. Upon completion of both surveys, parents are emailed Amazon gift card claim codes for themselves and their teens (Fig. 1). Additionally, if HbA1c values of the teen were not measured in the clinic during a follow-up period, similar to the enrollment time point, an at-home HbA1c kit is mailed to the family to be completed during the follow-up window. If an HbA1c kit is not returned to the laboratory within 2 weeks after it was sent to the family, the parents receive weekly reminder texts for their teen to complete and return the kit.

Recruitment and enrollment outcomes were analyzed and compared between in-person and remote procedures through October 2020 using chi-square tests to compare in-person and remote outcomes. Participant engagement rates through December 2020 were also analyzed using independent samples *t*-tests and compared with feasibility benchmarks established in the original protocol.

## RESULTS

### Participants

As seen in Table 1, during in-person recruitment from December 2019 to March 2020, RAs across both sites approached approximately 5 families per day. After transitioning to the remote recruitment procedure (July–October 2020), RAs called approximately six families per day across sites. Through the remote recruitment protocol more families were approached, but when accounting for unanswered calls, significantly fewer families heard the recruitment summary over the phone. Of the families who did answer the recruitment calls, there was no significant difference between those who screened compared to in-person approaches.

### Recruitment

No statistically significant differences in recruitment in teen demographics (teen's age, race, or sex) were observed between in-person and remote recruitment (Table 1). Though not statistically significant, White, Non-Hispanic teens showed interest more often (difference in race/ethnicity for screening was not significant between in-person and remote) and screened eligible more frequently than any other demographic group during both in-person procedures and remote procedures (no significant difference in race/ethnicity for eligibility or enrollment between in-person and remote protocols). We observed higher rates of girls screening eligible than boys both in-person and after transitioning to a remote protocol, but the gender difference between in-person and remote enrollment was not significant. Finally, a slightly higher percentage of teens who enrolled in-person use CGMs as part of their diabetes management than those enrolled remotely (62% and 72% respectively), but the difference in device use between in-person and remote enrollment was not significant ($\chi^2 = .53, p > .05$).

### Enrollment

Participation rates of eligible families were analyzed and compared between in-person and remote procedures. In-person recruitment efforts yielded 28 eligible families (29% of the 95 who agreed to screen in-person) and 21 were consented and enrolled, for a participation rate of 75% of eligible families. Remote recruitment efforts for this period yielded 38 eligible families (38% of the 99 who agreed to screen remotely) and 25 of those families have enrolled, for a participation rate of 66% of eligible families.

The reasons for not enrolling were analyzed and compared between in-person procedures and remote procedures. During in-person recruitment, seven eligible families were not enrolled (25% of those who screened eligible in person) most frequently due to not having enough time. For remote enrollment, 13 families (34% of those who screened eligible remotely) did not enroll, most frequently due to the family not responding to attempts to schedule the enrollment visit.

**Table 1** | Demographic characteristics

| | In-person *N* (%) or *M* (SD) | Remote *N* (%) or *M* (SD) | $\chi^2/t$ (*df*) |
|---|---|---|---|
| Total encounters | 455 | 667 | |
| Encounters that heard recruitment summary | 210 (46)* | 233 (35)* | 14.25 (1) |
| Encounters that screened | 95 (45) | 99 (42) | 0.34 (1) |
| *White, Non-Hispanic* | 60 (63) | 72 (73) | |
| *Ethnic, Racial minority* | 33 (35) | 25 (25) | 2.11 (2) |
| *Race not indicated* | 2 (2) | 2 (2) | |
| *Male* | 50 (53) | 45 (45) | |
| *Female* | 45 (47) | 53 (54) | |
| *Non-binary* | 0 (0) | 1 (1) | 0.87 (1) |
| Encounters that screened eligible | 28 (29) | 38 (38) | 1.72 (1) |
| *White, Non-Hispanic* | 15 (54) | 24 (63) | |
| *Ethnic, Racial minority* | 11 (39) | 13 (34) | 1.09 (2) |
| *Race not indicated* | 2 (7) | 1 (3) | |
| *Male* | 8 (29) | 13 (34) | |
| *Female* | 20 (71) | 25 (66) | 0.24 (1) |
| Encounters that enrolled | 21 | 25 | 0.65 (1) |
| *White, Non-Hispanic* | 12 (57) | 18 (72) | |
| *Ethnic, Racial minority* | 7 (33) | 6 (24) | 1.27 (2) |
| *Race not indicated* | 2 (10) | 1 (4) | |
| *Male* | 5 (24) | 8 (32) | |
| *Female* | 16 (76) | 17 (68) | 0.38 (1) |
| % Engagement with interactive texts | | | |
| *Overall teen response* | 87 (24) | 93 (10) | 1.14 |
| *Overall parent response* | 85 (25) | 92 (13) | 1.22 |
| % Engagement with interactive texts by group | *n* = 12 | *n* = 8 | |
| *PA group* | 85 (26) | 89 (9) | 0.42 |
| | *n* = 9 | *n* = 16 | |
| *EDU group* | 89 (22) | 95 (10) | 0.94 |
| A1c collection | 95.2% | 91.7% | |

*indicates difference between in-person and remote *$p < .001$.

### Engagement

Participant engagement rates were analyzed and compared between those enrolled in-person and those enrolled remotely. We defined engagement as any response to the interactive text messages. Engagement rates were calculated by dividing the number of responses by the total number of texts sent to each participant (Table 1). Teens and parents that enrolled pre-pandemic responded at similar rates to the interactive text messages. On average, teens assigned to the Diabetes Education group responded at similar rates as teens assigned to the PA group. Teens and parents enrolled after the study team pivoted to remote recruitment and enrollment procedures responded to an average of at least 90% of all the interactive text messages. Teens assigned to both the Diabetes Education group and the PA group responded to a majority of their interactive text messages.

From July through October 2020, 12 baseline A1c kits were sent to participants' homes with a 92% completion rate. Three kits were sent for the 3-month follow-up period, with a 33.3% completion rate. Ten kits were sent for the 6-month follow-up period with a 60% completion rate. Parents cited being on an extended trip away from home or having their teen be responsible for sending back the kit as reasons why the kits were not returned. Overall completion rate of at-home A1c kits is comparable to the data collection rate of point-of-care A1c values from in-person clinic visits.

Across dyads at 3- and 6-month follow-ups, 100 total surveys have been remotely administered thus far, with a completion rate of 90%.

### Feasibility

The feasibility of the remote protocol was analyzed using the metrics established during the design of the intervention. The benchmark for texting engagement was set at >70% response rate. Of the dyads enrolled remotely thus far, teens have demonstrated an overall engagement rate of 93% (±10%) and parents have demonstrated an overall engagement rate of 92% (±13%), exceeding the benchmark, and demonstrating the feasibility of this

component of the study. The benchmark for follow-up data collection was set at an 85% completion rate. Remote enrollment follow-up data include follow-up teen and parent surveys, and A1c kits. Through December 2020, 90% of all 3- and 6-month remotely administered surveys have been completed, demonstrating the feasibility of follow-up survey data collection. Thus far, remotely enrolled participants have yielded a participant retention rate of 96%, also demonstrating remote feasibility. In addition, 73% of A1c kits across all time points were completed, demonstrating a rate slightly below the feasibility metric benchmark.

## DISCUSSION

The transition from an in-person protocol to a remote protocol in response to the COVID-19 pandemic has successfully emulated key components of in-person procedures while presenting some differences throughout the participant experience. Specifically, the ability to communicate with the family face-to-face during enrollment via Zoom, the utilization of identical materials for remote and in-person enrollments, and the subsequent participant interaction with the study materials by sending physical copies directly to their home all aim to maintain fidelity to the in-person protocol. The flexibility of the adapted remote procedures offers families the option of completing their enrollment visit from their home within their preferred timeline. This was not accommodated during in-person procedures, as recruitment and enrollment occurred during clinic visits, and some families declined to participate because they could not stay after their visit given the need to return to school or work. The nature of the automated texting intervention, originally designed to increase potential translation of the intervention, suits the remote procedures well. The likelihood that teens and parents have increased access and spend more time on devices due to increased reliance on technology during COVID-19 may explain the high texting engagement rates seen thus far. The introduction of at-home A1c kits can be mutually beneficial to the data collection process and participants, as many appreciate receiving this information when they were not able to receive an A1c lab test in-person. While we observed higher levels of females than males screening eligible for the study, this was expected based on higher rates of clinically significant diabetes distress observed among adolescent girls versus boys [8], and the rates were not different based on the mode of recruitment. The similarities observed in the race, ethnicity, and gender characteristics of families who showed interest and enrolled in THR1VE! over the past 8 months, indicate that transitioning to a remote protocol did not alter the rates of recruitment of families by demographic factors.

### Limitations

The remote procedures offer a new subset of challenges to recruitment and enrollment. Due to COVID-19, many participants have utilized telehealth for their clinic visits. Observed differences in remote telehealth clinic appointments between sites are due to regional responses to upticks in locally reported COVID-19 cases. While there are many benefits of telehealth clinic visits, challenges exist, particularly related to obtaining data on glucose monitoring and lab values for A1c. Families can become unresponsive during the process of attempting remote recruitment and scheduling an enrollment time, which made it more likely to lose contact with a family during remote procedures compared to in-person procedures. Follow-up data may be missing due to the parent or teen being nonresponsive to the initial email and text, as well as follow-up reminders.

### Future directions

As more providers and families opt to return to in-person diabetes clinic visits, both clinical research sites plan to transition to a hybrid recruitment model. In this hybrid model, RAs will enter the clinic once or twice a week to recruit potentially eligible families as well as call families who have telehealth visits. Families with upcoming in-person clinic visits will be called a week ahead of their appointment and given the opportunity to meet with research staff in-person at the time of their visit, or screen and enroll remotely. The aim is to reapproach families who may not have otherwise answered the phone or became unresponsive during remote recruitment. This hybrid model aligns with findings that persistent and varying methods of recruitment increase the participation of underrepresented racial and ethnic minorities in clinical research trials [9].

While the impact of COVID-19 on the future of clinical trials remains uncertain, we expect to see more clinical trials develop remote procedures to adjust to social distancing practices. Ongoing and future studies may develop similar remote protocols to accommodate families and clinics who will continue to prefer contactless methods. In conjunction with digital protocol adaptations, remote clinical trials must prioritize flexibility and accessibility to maintain participant retention. The demonstrated feasibility of our remote recruitment, enrollment, and engagement protocols emphasizes the importance of prioritizing patient-centered clinical trial procedures.

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### Compliance with Ethical Standards

**Conflicts of Interest:** All authors declare that they have no conflicts of interest.

**Ethical Approval:** All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

**Informed Consent:** Informed consent was obtained from all individual participants included in the study.

Transparency Statements

1. The study was pre-registered at clinicaltrials.gov Identifier: NCT03845465.
2. The plan for this secondary analysis was not formally pre-registered, but the analysis plan for the larger study was pre-registered.
3. De-identified data from this study are not available in a public archive. De-identified data from this study will be made available (as allowable according to institutional IRB standards) by emailing the corresponding author.
4. Analytic code used to conduct the analyses presented in this study are not available in a public archive. They may be available by emailing the corresponding author.
5. Materials used to conduct the study are not publicly available.

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