LESSONS ON RESILIENT RESEARCH: ADAPTING THE TRIBAL TURNING POINT STUDY TO COVID-19

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Abstract: Tribal Turning Point (TTP) is a community-based randomized controlled trial of a lifestyle intervention to reduce risk factors for type 2 diabetes in Native youth. TTP began in 2018 and was interrupted by the COVID-19 pandemic in 2020. In this paper we aimed to understand 1) how the pandemic impacted TTP's operations, and how the TTP team successfully adapted to these impacts; 2) how the effects of COVID-19 and our adaptations to them were similar or different across TTP's research sites; and 3) lessons learned from this experience that may help other Native health research teams be resilient in this and future crises. Using a collaborative mixed methods approach, this report explored five a priori domains of adaptation: intervention delivery, participant engagement, data collection, analytic strategies, and team operations. We derived three lessons learned: 1) ensure that support offered is flexible to differing needs and responsive to changes over time; 2) adapt collaboratively and iteratively while remaining rooted in community; and 3) recognize that relationships are the foundation of successful research.

INTRODUCTION

Tribal Turning Point (TTP) is a randomized controlled trial that aims to reduce risk factors for type 2 diabetes in American Indian (Native) youth. Participants were recruited from three community-based research sites in Arizona and New Mexico: two rural communities within the Navajo Nation and one urban site in the Phoenix metropolitan area. The TTP program is a culturally adapted, group-based lifestyle intervention administered by trained community members employed by the University of Colorado as Professional Research Assistants (PRAs).

This study builds on the success of an earlier pilot study (Sauder et al., 2018) and will rigorously evaluate the effect of TTP on diabetes risk factors in a larger sample of Native youth, with the long-term goal of disseminating this evidence-based program to other Native communities.

Like nearly all research studies, TTP was abruptly impacted in early March 2020 when the spread of SARS-CoV-2 led the World Health Organization to declare COVID-19 a pandemic. Since that time, the TTP team (PRAs, managers, and investigators) has collaborated to adhere to study protocols in the face of ongoing challenges. This report explores the characteristics and strategies that have allowed the TTP clinical trial to progress during the first 18 months of the global pandemic. Specifically, it addresses: (1) how the COVID-19 pandemic impacted TTP's operations, and how the TTP team successfully adapted; (2) how the effects of COVID-19 and our adaptations to them were similar or different across TTP's reservation and urban research sites; and (3) what lessons the TTP team learned from this experience that may help other Native health research teams be resilient in this and future crises.

METHODS

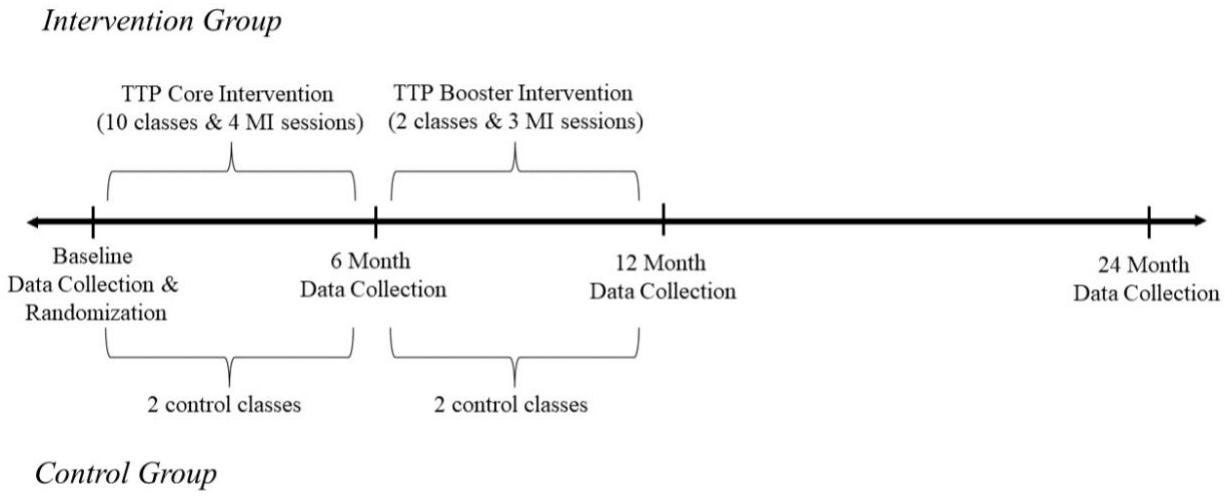
TTP Protocol

TTP is a youth-focused adaptation of the Diabetes Prevention Program (DPP), which has demonstrated efficacy in adults and has been disseminated nationally (Diabetes Prevention Program Research Group, 2009; Albright & Gregg, 2013). The TTP clinical trial enrolled Native youth aged 7-10 years with overweight or obesity (age and sex-specific BMI >=85th percentile) and who had at least one caregiver willing to participate in the program with them. This age range was targeted because of the greater potential for changing health behaviors before they are well-established and before the metabolic transitions of puberty begin.

The original study design included plans to collect data on anthropometric, metabolic, and behavioral risk factors for type 2 diabetes at the baseline visit, at 6 months (midway through the TTP program), at 12 months (immediately after completing the program), and at 24 months (1 year after completing the program). After the baseline visit, child-caregiver dyads were randomized to either the intervention group or a control group. Participants were recruited in "waves," with new intervention and control group classes starting every six months.

Figure 1 illustrates the 24-month timeline of study activities for the intervention (top) and control (bottom) group participants. The TTP intervention includes 12 in-person group classes and

Figure 1. Tribal Turning Point study timeline by randomization group

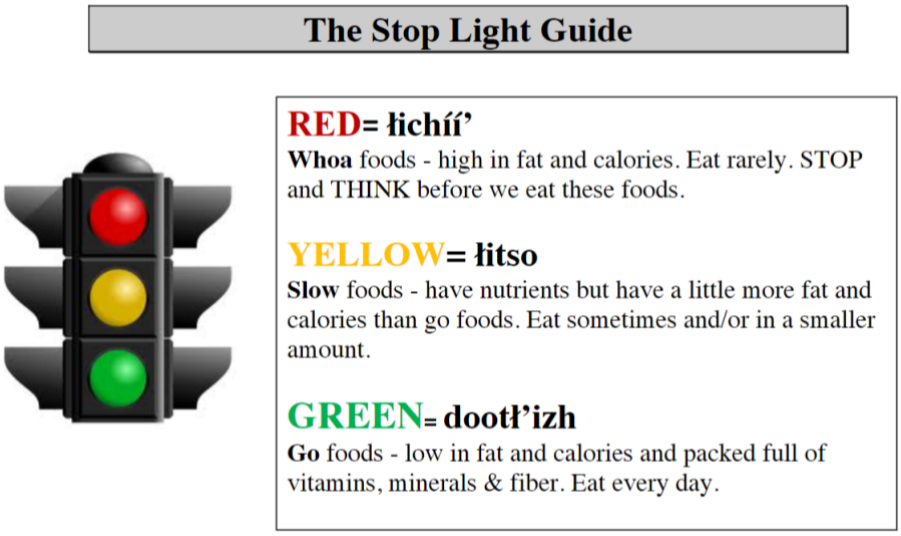


7 in-person individual family support sessions that utilize motivational interviewing (MI) strategies to assist participants in meeting TTP goals. These classes and sessions were held on weekday evenings over the course of one year. Intervention classes included a guided group workout, a healthy meal, and interactive lessons about nutrition, physical activity, setting goals, and maintaining healthy habits that integrate culture and language. PRAs used detailed manuals developed during the pilot study to guide program delivery, which included concrete and easy-to-understand learning tools (e.g., the Stop Light Guide, adapted for TTP from Epstein et al., 2008; see Figure 2). Classes and individual sessions occurred every week during the first six months of TTP (the "core" portion) and every month in the latter half of the program (the "booster" portion). Participants could earn "Wellness Bucks" for attending the program and completing goal tracker worksheets, which they redeemed for prizes like bikes, MP3 players, and weaving kits at the end of the program.

Families randomized to the control group received four in-person group classes held on weekday evenings over the course of one year. Topics for these interactive classes included bike safety, sun safety, CPR and first aid, substance abuse, bullying, art as medicine, and recycling. Whenever possible, classes were led by local Native experts to help expose families to additional programs and opportunities in their community.

Two PRAs were hired at each research site in spring 2018. PRAs are community members with varying amounts of public health education and experience, who receive ongoing training in data collection and health promotion. Participant recruitment began in summer 2018. At the

Figure 2. The Stop Light Guide



Navajo Nation sites, recruitment occurred primarily through connections with local schools and Indian Health Service facilities. In Phoenix, partners at the Phoenix Epidemiology and Clinical Research Branch (PECRB) of the National Institute of Diabetes and Digestive Kidney Disease (NIDDK) helped recruit family members of those enrolled in other research studies, and PRAs built connections with urban Native community organizations and school-based Native American education programs.

Mixed Methods Exploration of COVID-19 Adaptations

We used a collaborative and strength-based approach to explore the TTP team's experiences during the COVID-19 pandemic. Our process was intentionally iterative, with time and space set aside for both personal reflection and team dialogue. To ground our exploration, we began by creating a timeline (Figure 3) of TTP activities during the pandemic based on a review of study documents including protocols, data collection procedures and forms, e-mail communications, photographs, tracking spreadsheets, and Institutional Review Board (IRB) submissions. The timeline informed both the qualitative and quantitative data analyses and was in turn revised based on the results gleaned from these analyses. While it began as a visualization of TTP's activities alone, through team dialogue the timeline expanded to include many tribal, state, institutional, and national events and milestones that influenced TTP's adaptations. The final version illustrates the complexities of adapting a multi-component, multi-site intervention study to the dynamic, and sometimes conflicting, contexts of different communities.

Figure 3. Timeline of COVID-19 activities and contextual factors

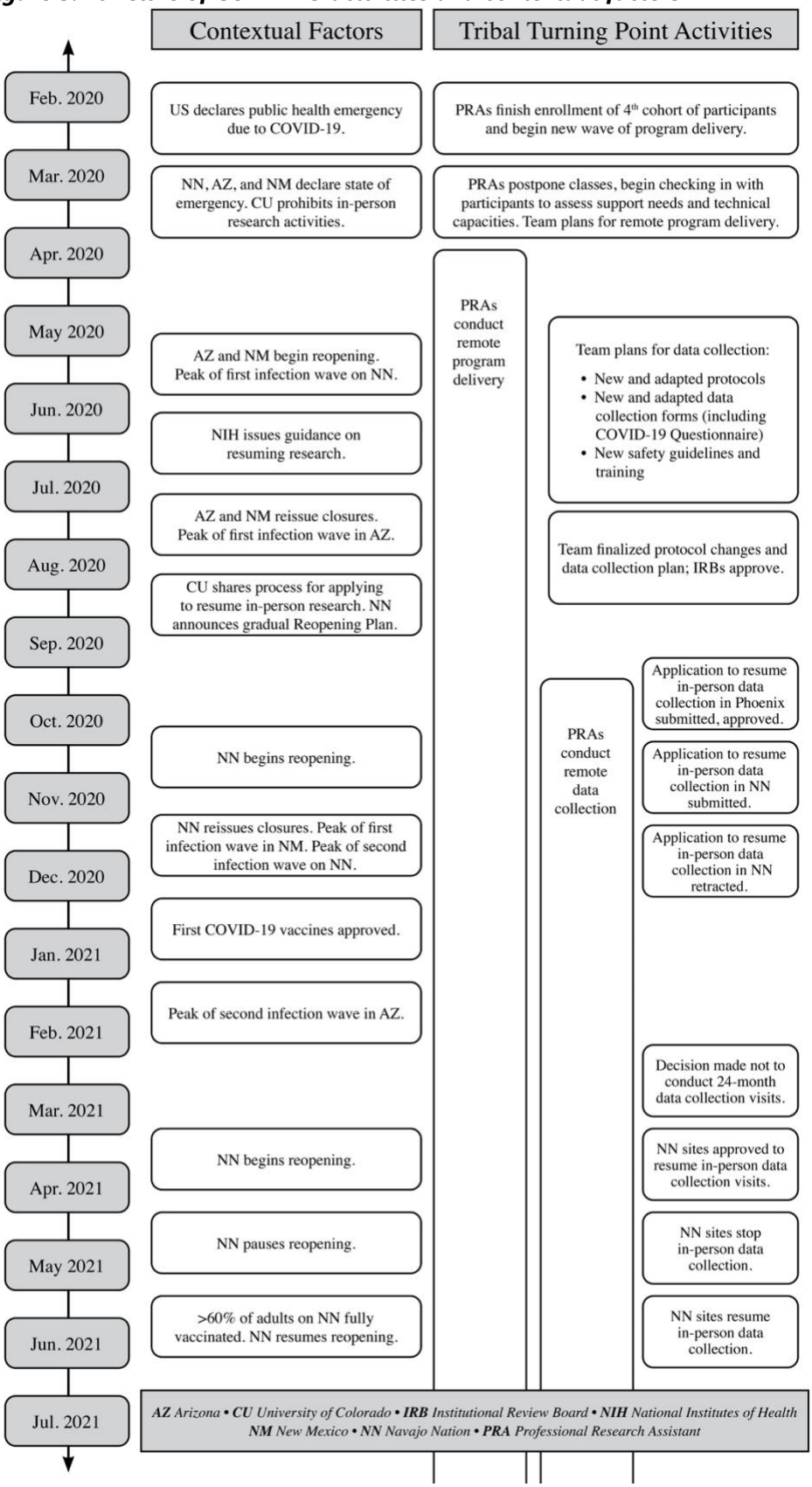
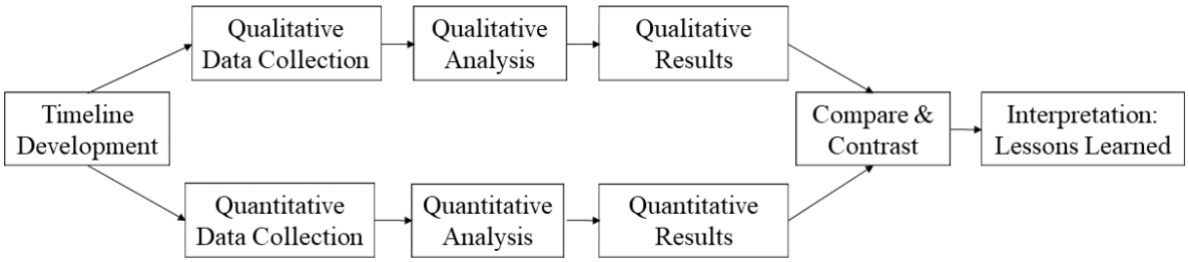


Figure 4. Mixed methods triangulation design convergence model used to explore TTP experiences during COVID-19



We used a mixed methods triangulation design called the convergence model to guide our exploration (Figure 4) (Creswell & Plano Clark, 2017). The purpose of the convergence model is to combine differing and complementary data by analyzing qualitative and quantitative data concurrently and separately. The convergence model enables researchers "to end up with valid and well-substantiated conclusions about a single phenomenon" (Creswell & Plano Clark, 2017, p. 65), in this case, TTP's experiences during COVID-19. Data were gathered and analyzed for each of five domains of interest (intervention delivery, participant engagement, data collection, analytic strategies, and team operations) that were determined a priori through discussions among managers and investigators.

Analysis

Qualitative Analysis

The TTP managers (one project manager [R.S.] and one data manager [J.B.]) conducted a rapid qualitative analysis to identify similarities and differences in team members' experiences of COVID-19 adaptations across the research sites. Rapid qualitative analysis is an efficient, accurate, action-oriented approach that is ideal for answering clearly defined research questions (Hamilton, 2013, 2020). Rapid qualitative analysis has been found to produce valid, reliable findings in a shorter timeframe than traditional qualitative analysis, minimizes the burden on the research team, and is well-suited to projects that aim to yield practical guidance (Gale et al., 2019; Vindrola-Padros et al., 2020). As a quality assurance and performance evaluation project, this work was exempt from Institutional Review Board oversight.

The managers developed a 10-question semi-structured guide based on the draft timeline and the five domains of interest (Table 1). The project manager invited the staff at all three sites to participate in the analysis by sharing their experiences of TTP's COVID-19 adaptations; four of

the five agreed. The project manager met with those four PRAs (P.B., D.G., S.N., and D.Y.) via Zoom to discuss the questions; these site-specific conversations were then transcribed. Transcriptions were sent to each PRA so that they could ensure their perspectives were accurately portrayed, and the managers then summarized each one using a standard template. After ensuring the consistency and completeness of the summaries, the managers consolidated the key points into a matrix with rows for each domain and columns for each site. The managers reviewed the matrix independently to identify emergent patterns of similarity and difference, then met to discuss the predominant themes.

Table 1
Questions asked by the project manager of the PRAs during site-specific conversations, by domain

Domains	Questions
Timeline	• What jumps out to you on this timeline? Why is it important? • Is anything missing from this timeline? If so, what?
Program Delivery	• Tell me about making the shift from doing TTP classes and individual sessions in person to doing it remotely.
Participant Engagement	• Tell me about how COVID-19 affected TTP participants in your community. • Tell me about your experiences communicating with participants during the pandemic.
Data Collection	• Tell me about what your experience was like when we were developing the new data collection visit protocols, the Safety Plan, and all the new forms that went along with them. • Tell me about when you first started doing fully remote data collection visits. What was that like? • Tell me about what it was like doing in-person visits in new ways.
Team Operations	• How did you stay connected with the rest of the TTP team during the pandemic?
Other	• Are there any stories you can share that show TTP's success or resilience during COVID?

Quantitative Data

Quantitative data include the self-reported effects of COVID-19 on TTP participants, which address the participant engagement domain, and data comparing pre-COVID-19 and during-COVID-19 program attendance and 12-month retention, which address the program delivery and data collection domains, respectively. All quantitative data were gathered by PRAs and collaborating partners at ACKCO (an American Indian professional services firm) and at the NIDDK PECRB. Quantitative data used in this report were extracted from the secure TTP

Research Electronic Data Capture (REDCap) database. The data manager cleaned and descriptively analyzed all quantitative data in SAS version 9.4.

Triangulation and Integration

After separately analyzing the qualitative and quantitative data, key findings from each analysis were integrated by domain to address the first two research areas: COVID-19's impacts on TTP and its adaptations, and how these experiences differed across sites. These data were then integrated across domains to address the third research area: lessons learned from TTP's experiences that may help other research teams. These interpretations were discussed and refined by PRAs, managers, and investigators.

RESULTS

Figure 3 presents a timeline of major events and changes to TTP, as well as key contextual events that shaped these adaptations. While initial reports of COVID-19 began to circulate in early 2020, the TTP team was recruiting and enrolling a new cohort of participants at all three sites. As the PRAs transitioned from data collection to program delivery, the University of Colorado, the Navajo Nation, and state governments issued emergency orders and imposed new safety measures. Throughout the pandemic, the team adapted study operations to the dynamic local influences and corresponding guidance from these multiple institutions and communities, which sometimes varied across research sites. The results of our exploration of adaptations and their effects (aim 1) are summarized in Table 2; results illustrating similarities and differences across sites (aim 2) are summarized in Table 3.

Table 2
Summary of aim 1 results: Effects of and adaptations to COVID-19 by domain

Domain	Qualitative Results	Quantitative Results
Intervention Delivery	• The team transitioned from in-person to remote delivery in response to COVID-19 shutdowns. • Remote delivery protocol development was collaborative and iterative.	• Mean program attendance during the pandemic was 9 classes/sessions, similar to the pre-pandemic mean of 10 classes/sessions.
Participant Engagement	• Some participants struggled to remain engaged in TTP during the pandemic due to stress, communication barriers, and competing priorities. • The team's flexibility, creativity, and empathy were key to sustaining engagement.	• 7% of children and 18% of adults had or likely had COVID-19. • 25% of families lost a loved one to COVID-19. • 54% of families experienced moderately or extremely negative impacts from COVID-19.

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Table 2
Summary of aim 1 results: Effects of and adaptations to COVID-19 by domain

Domain	Qualitative Results	Quantitative Results
Data Collection	• The study team collaborated to create safety plans, visit protocols (including for adapted in-person visits and new remote and hybrid visits), and data collection forms. • Coordinating and implementing changes was sometimes stressful and required compromise, but was ultimately worthwhile because it ensured participant safety.	• 71% of participants completed 12-month BMI measures before COVID-19, as compared to 53% during COVID-19. • 62% of participants completed 12-month insulin measures before COVID-19, as compared to 36% during COVID-19.
Data Analysis	• TTP's existing quantitative and qualitative analysis strategies and guiding frameworks will address the potential effects of COVID-19 on study outcomes. • Analyses will control for timing of data collection in reference to baseline, as collection of some measures were delayed due to COVID-19 restrictions. • COVID-19 will likely influence the way study results are interpreted.	• N/A
Team Operations	• Communication across TTP sites was already primarily virtual before COVID-19, but the shift to remote work required creative and flexible solutions, especially for intra-site collaboration. • During the pandemic, new types of support were provided by managers to PRAs and PRAs to one another.	• N/A

Table 3
Summary of aim 2 results: Similarities and differences of COVID-19 across sites by domain

Domain	Qualitative Results	Quantitative Results
Intervention Delivery	• PRAs at the Navajo Nation sites used mainly phone calls and mail to deliver the intervention remotely. • PRAs in Phoenix used mainly a mix of phone calls and video-based platforms to deliver the intervention remotely. • All PRAs were highly flexible to meet participant needs.	• Mean program attendance during the pandemic was 14 classes/sessions in Phoenix and 10 classes/sessions at the Navajo Nation sites.
Participant Engagement	• PRAs at all sites responded to participant experiences and needs with empathy and patience.	• 19% of child participants in Phoenix and 4% in Navajo Nation had or likely had COVID-19. • 38% of adult participants in Phoenix and 14% in Navajo Nation had or likely had COVID-19. • 38% of families in Phoenix and 22% in Navajo Nation lost loved ones to COVID-19. • 31% of families at the Phoenix site and 59% at the Navajo Nation sites reported experiencing negative impacts from COVID-19.

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Table 3 continued
Summary of aim 2 results: Similarities and differences of COVID-19 across sites by domain

Domain	Qualitative Results	Quantitative Results
Participant Engagement	• PRAs at all sites responded to participant experiences and needs with empathy and patience.	• 19% of child participants in Phoenix and 4% in Navajo Nation had or likely had COVID-19. • 38% of adult participants in Phoenix and 14% in Navajo Nation had or likely had COVID-19. • 38% of families in Phoenix and 22% in Navajo Nation lost loved ones to COVID-19. • 31% of families at the Phoenix site and 59% at the Navajo Nation sites reported experiencing negative impacts from COVID-19.
Data Collection	• In-person data collection resumed earlier at the Phoenix site than at the Navajo Nation sites in response to local conditions. • Each site had its own specific visit protocols to address unique geographical and institutional requirements.	• Completion rates for 12-month BMI measures during COVID-19 were 48% in Phoenix and 54% at the Navajo Nation sites. • Completion rates for 12-month insulin measures during COVID-19 were 48% in Phoenix and 33% at the Navajo Nation sites.
Data Analysis	• N/A	• N/A
Team Operations	• Team communication was often more challenging at the Navajo Nation sites than the Phoenix site due to more limited phone and internet connectivity.	• N/A

Intervention Delivery

In the first weeks of the shutdown the TTP team collaborated to determine how best to deliver the program remotely. The PRAs first drew on methods used before the pandemic to make up sessions with families who had missed a TTP session, which consisted of mailing class handouts to the participants and speaking with them by phone to review the main points and answer questions, as well as conducting individual sessions by phone. Based on this existing make-up delivery system and on discussions with the PRAs, the project manager created a brief set of guidelines for remote program delivery during COVID-19 that included information about additional remote delivery modes (e.g., e-mail and videoconferencing), instructions to help participants prepare for remote sessions, and changes to the Wellness Bucks reward system. The PRAs, as experts in delivering the TTP curriculum, used the existing coach's notes, individual session scripts, and participant handouts to determine the key points of each class and how best to cover them remotely. While the written content and session objectives remained unchanged, some program activities designed for in-person classes, such as group reflections and active multi-player games, had to be adapted, condensed, or removed for virtual individual delivery.

Remote program delivery was challenged by varying technological capacities across and within sites. Some participants on the Navajo Nation lacked internet access, and others had poor cell phone service. Only a few were able to receive e-mailed materials or conduct remote classes using videoconferencing; most communicated with the PRAs primarily by text messages and phone calls and received materials by mail or remote drop-offs. Ultimately, the PRAs on the Navajo Nation continued to use a remote delivery method similar to the original protocol for make-up classes. In contrast, at the Phoenix site the PRAs were able to record videos of the content for each class, e-mail or text the video links and handouts to participants, and then review key points with most of the participants via HIPAA-compliant videoconferencing platforms, such as Zoom. Later in the pandemic, the Phoenix PRAs were also able to conduct live classes via Zoom. Individual session delivery methods followed similar patterns across the sites. PRAs at all sites worked closely with individual families to assess and meet their needs.

The transition to remote program delivery began in March 2020 and was implemented at all sites by June. The PRAs attribute the success of remote delivery to reducing class content to just the essential points, which meant skipping some details but made the material more accessible and comprehensible to participants. PRAs also highlighted the importance of their share-then-review method, which included extra communication with participants prior to each remote class to ensure they were prepared to discuss the material. The principal investigators also allowed the PRAs to continue to deliver "core" program content after the 6-month midpoint, recognizing that many participants had not been able to engage with the program in the early stages of the pandemic (the same allowance had been made pre-pandemic when families missed sessions). Such flexibility allowed the PRAs and participants time to catch up on classes and individual sessions that had not been completed. This combination of strategies led to attendance rates that closely matched pre-pandemic levels: on average, participants in the intervention group completed 10.16 classes and individual sessions during the pandemic, as compared to 9.71 pre-pandemic (see Table 4), out of a possible total of 19 (12 classes and 7 individual sessions). The mean number of classes/sessions was similar across sites during the pandemic (10.22 at the Navajo Nation sites and 13.86 in Phoenix). Pre-pandemic attendance differences across sites (9.12 classes/sessions at the Navajo Nation sites vs. 17.50 in Phoenix) are attributable to the greater number of pre-COVID-19 intervention participants at the Navajo Nation sites (n = 26) as compared to Phoenix (n = 2).

Table 4
Intervention program attendance pre-pandemic vs. during pandemic, by location and overall (n=85)

	Navajo Nation Sites		Phoenix Site		Overall	
	Pre-Pandemic (*n*=26)	During Pandemic (*n*=46)	Pre-Pandemic (*n*=2)	During Pandemic (*n*=11)	Pre-Pandemic (*n*=28)	During Pandemic (*n*=57)
Mean Number (SD) of Intervention Classes/ Sessions Completed	9.12 (6.89)	10.22 (6.73)	17.50 (0.50)	13.86 (6.34)	9.71 (6.98)	10.16 (6.66)
Mean Percent of Intervention Classes/ Sessions Completed	47.98%	53.78%	92.11%	72.93%	51.13%	53.46%

Table 5
Participant-reported physical and mental health impacts of COVID-19, by location and overall (n=89)

	Navajo Nation Sites (*n*=73)	Phoenix Site (*n*=16)	Overall (*n*=89)
Enrolled children who had or likely had COVID-19	3 (4.11%)	3 (18.75%)	6 (6.74%)
Enrolled adults who had or likely had COVID-19	10 (13.70%)	6 (37.50%)	16 (17.98%)
Families who lost a loved one to COVID-19	16 (21.92%)	6 (37.50%)	22 (24.72%)
Families who experienced moderately or extremely negative impacts from COVID-19	43 (58.90%)	5 (31.25%)	48 (53.93%)

Participant Engagement

COVID-19 imposed a drastic change in lifestyle, priorities, and stress levels for TTP participants. Table 5 summarizes data from a COVID-19 questionnaire administered to TTP families at all visits during the pandemic, from August 2020 through August 2021 (the most recent data from each participant is used, as some provided this data at multiple visits), which illustrates some of the self-reported physical and mental effects of the pandemic. While relatively few child participants likely had COVID-19, nearly 1 in 5 adult participants reported that they were likely infected, and 1 in 4 families lost a loved one to the pandemic. A higher percentage of families at the Navajo Nation sites reported that they had experienced moderately or extremely negative impacts as a result of the pandemic compared to the Phoenix site.

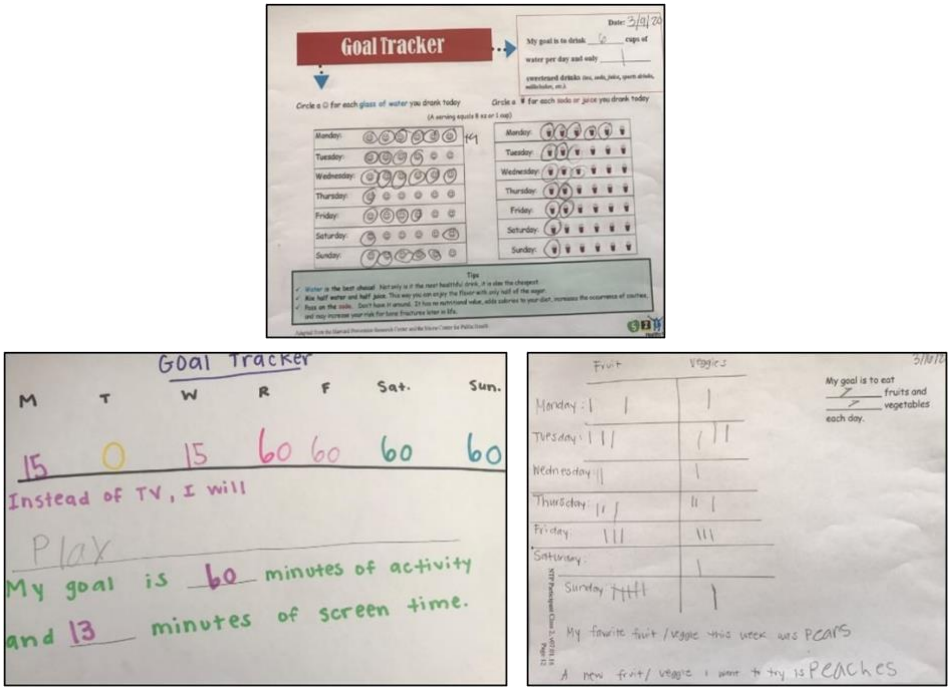
When the pandemic first began, the PRAs contacted participants to see how they were doing. In the ensuing months, the PRAs continued to check in and continuously provided participants with important COVID-19 safety information via culturally appropriate infographics, flyers, and electronic resource lists shared via mail, e-mail, text messages, and social media. The same array of communication methods was used to offer updates on study changes and to send reminders about classes and individual sessions. At one of the Navajo Nation sites, a PRA volunteered with community organizations to help provide food, water, and hygiene products to families in quarantine, including some TTP participants. At all sites the PRAs also continued traditional retention strategies, such as sending birthday cards to child participants.

Since families had not planned to engage in TTP via virtual methods when they enrolled, the team had to adapt to the specific technological capacities of each household. The PRAs had to creatively find ways to adhere to the spirit and intent of TTP while allowing participants to engage more effectively from home. PRAs demonstrated flexibility in finding a consistent day and time each week to meet with each family, but also recognized the need for patience as families made the difficult shift to working and learning from home and dealt with the physical and mental strains of pandemic life.

At the Navajo Nation sites, where many families traveled to their PO boxes at infrequent intervals, PRAs sometimes dropped off class materials at participants' doorsteps or sent materials by e-mail if families had access to home internet. Even in our urban site, where most participants could receive class materials via e-mail, many families lacked home printers and struggled to complete class worksheets. When families told the PRAs they were having trouble accessing enough copies of the TTP goal trackers, the PRAs encouraged them to make their own and text photos to the PRAs when the trackers were complete (see Figure 5).

The PRAs emphasized the importance of relying on their existing interpersonal connections with participants to sustain engagement. Responses were often slow to come; the PRAs reacted with patience and empathy. During some individual sessions the PRAs simply listened, allowing participants to unburden themselves of their worries and providing validation of their emotional experiences. During some class review calls, PRAs asked a question only to learn from a child participant that their parent had left mid-class to run an errand. One PRA said participant engagement during COVID-19 sometimes felt like digging a ditch with a spoon. Yet, the PRAs were able to sustain their relationships with the majority of the participants, as illustrated in the attendance data described in the previous section.

Figure 5. A typical TTP goal tracker (top) and two participant-made goal trackers (bottom)



Data Collection

Data collection was not conducted during the first several months of the pandemic, as TTP's wave-based recruitment structure results in six-month gaps between collection phases that aligned with the start of the pandemic. This allowed the TTP team to spend time discussing, developing, and editing thorough visit procedures that incorporated new safety measures and data collection strategies. Most of the discussion centered on how to minimize participant and staff contact during data collection visits. The result was a series of protocols offering a range of visit options, as well as a scheduling script to help the PRAs determine the most appropriate visit type for each family.

The fully remote visit protocol included instructions for PRAs to drop off visit materials (including paperwork, an accelerometer, a scale, a stadiometer, and gift cards) on the doorstep of a participant's home at an agreed-upon day and time, walk the family through the visit by phone or video, and then retrieve the completed paperwork and other materials from the doorstep. This visit type allowed for the collection of data to assess one of TTP's primary outcomes (i.e., height and weight, which participants could measure themselves with staff guidance), but not the other (i.e., a fasting venipuncture to measure insulin, which required in-person interaction between

PRAs and participants). The adapted in-person clinic protocol prioritized the data that could not be gathered remotely and detailed enhanced safety precautions. It also demarcated which data collection measures participants could be encouraged to complete remotely to reduce in-person exposure. In the "hybrid" visit option, only priority measurements took place in person and nearly all other data collection took place remotely. Additional adapted versions of these visit protocols (e.g., an in-person outdoor home visit protocol) were developed later as seasonal and institutional changes created new opportunities for innovative data collection methods.

The project manager drafted a COVID-19 Research Safety Plan containing basic information about COVID-19 and expectations for PRAs and participants around personal protective equipment, disinfecting, screening, and reporting. Many other supplemental documents were also created, such as a COVID-19 screening form that PRAs administered to participants before visits and a follow-up fact sheet provided to participants after visits with basic information about COVID-19 symptoms and what to do if exposed. In addition, various updates were made to existing data collection forms and the REDCap database.

After these initial documents were drafted by the project manager with input from the PRAs, each site team met repeatedly for several months to identify issues and suggest edits. For the Navajo Nation sites, this included adding questions to the scheduling script to find out more about where families lived before a drop-off (e.g., whether their road was likely to become muddy when it rained, precluding a remote drop-off). For the Phoenix team, this meant incorporating safety measures and screening questions required by TTP's partners at the NIDDK PECRB, who provide essential support for data collection at that site.

All PRAs received training on the final plans from the project manager via Zoom and were then asked to sign a code of conduct acknowledging they agreed to follow the safety requirements. The project manager followed up about safety questions and concerns on weekly Zoom meetings with each site, made documents available in a shared online drive, and provided periodic updates and reminders via e-mail. The visit protocols and safety plan were viewed as living documents and were continuously updated to address changing circumstances. As these new visit protocols, safety plans, and associated materials were developed and updated, changes were also made to the TTP Study Protocol. These documents were submitted to TTP's IRBs at the University of Colorado, the National Institutes of Health, and the Navajo Nation Human Research Review Board.

For the PRAs, the development of new documents was often stressful. Safety was everyone's priority, but varying institutional rules and differing interpretations of the emerging

scientific evidence led to some challenging conversations and necessitated compromises. In addition, these new multi-part visit protocols and additional safety precautions required a great deal more time and effort from the PRAs than traditional visits. Ultimately, however, the lengthy visit adaptation and reimplementation processes were perceived as worthwhile because they resulted in clear roles and responsibilities and protocols that flowed well. Although learning the new protocols was difficult for the PRAs, they witnessed the value of the changes when participants expressed their willingness to attend visits and their appreciation for the new safety requirements and options. The PRAs stated that the participants' cooperation and enthusiasm were the key to the success of data collection during the pandemic.

While remote data collection was implemented by all sites in September 2020, in-person data collection resumed at different times for each of the sites—in October 2020 at the Phoenix site and in May 2021 at the Navajo Nation sites—in response to varying local safety conditions. Approval processes were lengthy, as they involved submissions to multiple institutions. For the Phoenix site, approvals were granted by both the University of Colorado and the National Institutes of Health in late September 2020. However, when applications for the Navajo Nation sites were submitted to the University just weeks later, COVID-19 infections had begun to increase, and the applications were retracted. In-person research activities were not approved for the Navajo Nation sites until March 2021, were paused when the Navajo Nation reissued shelter-in-place orders in April 2021, and resumed in May 2021 when reopening recommenced. The team then continued to monitor local case rates and other metrics in each community to ensure that visits remained safe.

In early 2021, after reviewing data collection and retention data from the past year, TTP investigators made the difficult decision to forego the 24-month data collection visit at all sites in order to reallocate resources to 12-month data collection efforts. The changes in BMI and fasting insulin from baseline to 12 months are the primary outcomes of TTP; focusing the PRAs' time and energy on collecting this data was deemed essential to the evaluation of the TTP intervention. Amendments to the study protocols were submitted to and approved by all necessary IRBs, the Data Safety and Monitoring Board, and the NIH study sponsor in spring and summer 2021, and PRAs began informing participants of the change by letter and at visits.

Due to the collaborative efforts of the participants, PRAs, managers, investigators, and partners to adapt TTP's data collection activities, the number of participants completing 12-month visits increased steadily throughout spring and summer 2021. However, it was exceedingly difficult to schedule visits with some participants; even when scheduled, the increased complexity

of multi-part visits led in some cases to incomplete data (e.g., completed questionnaires but no specimens collected, or vice versa). As of August 2021, the 12-month retention rate among participants impacted by the pandemic remained lower than for that of participants who completed TTP prior to the pandemic for both primary outcomes (see Table 6). Completion rates for height and weight measures during the pandemic, which could be collected remotely, were similar across sites (54.44% at the Navajo Nation sites and 47.83% in Phoenix). Insulin completion was lower at the Navajo Nation sites (33.33%) than at the Phoenix site (47.83%), likely because the Phoenix team was able to conduct more in-person 12-month visits earlier in the pandemic, whereas the Navajo Nation teams had to gather remote data first, then re-engage participants to conduct partial in-person visits months later.

Table 6
12-month data on primary outcomes collected pre-pandemic vs. during pandemic (n=178)

	Navajo Nation Sites		**Phoenix Site**		**Total**	
Measurement (Outcome)	**Pre-Pandemic (*n*=61)**	**During Pandemic (*n*=90)**	**Pre-Pandemic (*n*=4)**	**During Pandemic (*n*=23)**	**Pre-Pandemic (*n*=65)**	**During Pandemic (*n*=113)**
Participants with complete height and weight (BMI) measures at 12 months	70.49%	54.44%	75.00%	47.83%	70.77%	53.10%
Participants with complete venipuncture (insulin) measures at 12 months	62.30%	33.33%	50.00%	47.83%	61.54%	36.28%

Analysis Strategies

Because TTP continues to recruit participants and deliver the program, data analysis has not yet begun. However, we suspect that the COVID-19 pandemic has impacted TTP participants in ways that will affect their anthropometric, metabolic, and behavioral outcomes. We do not anticipate difficulty in accounting for the effects of COVID-19, as longitudinal studies in which participants are enrolled over time must plan for time-based adjustments. Our existing analysis plan is therefore well suited to account for the potential "history effect" introduced by the pandemic (for an in-depth discussion of this effect and related implications of COVID-19 on study validity see Mara and Peugh, 2020). In short, the imposition of COVID-19 does not in itself change the analytical strategy to be employed, although it will likely change the way the findings are

interpreted. Moreover, power to detect significant program effects will be impacted if attrition is higher than was anticipated during the planning of the trial.

TTP also aims to explore multi-level factors related to participant engagement, program implementation, and potential for sustained delivery. COVID-19 presents an unexpected but measurable factor in TTP's implementation and will be addressed through data gathered in alignment with our guiding frameworks: the Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) model and the Practical, Robust Implementation and Sustainability Model (PRISM) (Glasgow et al., 1999; Feldstein et al., 2008; Glasgow et al., 2019). The Model for Implementation Design and Impact (MADI) is one tool with which we may elucidate the specific impacts of study adaptations on outcomes (Kirk et al., 2020).

Team Operations

Due to its community-based, multi-site structure TTP always utilized remote communication methods (e.g., phone calls, texts, e-mail, Zoom meetings) and shared documents via secure online servers (e.g., REDCap, cloud-based drives) to stay connected across hundreds of miles of distance. The project manager visited each site every few months and study-wide in-person meetings occurred annually. The pandemic halted in-person interactions, forcing the team to use only remote communication and to find new ways to support one another. This transition was especially challenging for the site-based PRA teams, which had previously worked together in shared offices. PRAs on Navajo Nation had more limited access to reliable internet connectivity at home than the PRAs in Phoenix, which impacted communications with both participants and the study team and required creative solutions, flexibility, and empathy from managers and fellow PRAs. However, all PRAs had to find new ways to do intra-site team activities that they had previously accomplished in person, including increased use of Zoom, phone calls, and text messages. PRAs were encouraged to bring home materials from the offices, and some additional equipment was purchased to support their remote work. The managers also sent the PRAs two "self-care" packages containing items such as cloth face masks, thermometers, scented candles, tea, seeds, and handwritten cards.

Managers strove to offer team-based support via weekly site-team Zoom meetings and monthly full-team Zoom meetings. Managers also provided interpersonal support through regular one-on-one calls, which gave PRAs a private space to share ideas, discuss their work, and ask for help. Some PRAs wanted more structure, and requested additional reminders and check-in calls;

others asked for more independence, such as working in evenings and on weekends to accommodate family care during the weekdays. TTP had always allowed for flexible schedules, including evening and weekend work, so that PRAs could adjust to participants' schedules; however, finding a balance between participant, PRA, and study needs during the pandemic required ongoing conversation. Sometimes Zoom meetings became phone calls if internet connections did not cooperate, and e-mailed notes were always sent after meetings to ensure key messages were not lost in broken audio. The PRAs acknowledged that the respect, clear communication, and genuine care demonstrated by the managers and investigators during the pandemic was crucial to the continuation of the study and added that these same characteristics were critical in their own relationships with the participants.

The PRAs also drew strength from their site teams. Several PRAs emphasized the importance of finding new ways to communicate with and support one another and how vital it was to have others to reach out to for encouragement in difficult times. Teamwork across sites was limited due to their physical separation and the vastly different circumstances in which they were operating. However, all of the PRAs expressed their appreciation for the opportunities to connect as a team that did take place, including trainings, debriefs, and staff meetings.

DISCUSSION

The qualitative and quantitative results of our exploration illustrate the deep impacts COVID-19 has had on TTP, the myriad ways in which the team has adapted to these difficult circumstances, and the primarily positive outcomes of these efforts. Intervention delivery and data collection transitioned to primarily remote methods, and sustaining engagement—with participants as well as within the study team—was challenged by technological limitations and the strains of adjusting to pandemic life. Creativity, flexibility, and clear communication across all levels of the study team emerged as essential features of TTP's resilient response. The fruits of these efforts are evident in the program attendance data, which are comparable to pre-pandemic levels and are similar across sites; however, the 12-month retention data illustrates that even the best adaptations cannot overcome all obstacles.

The results also illustrate the complexity of multi-site research adaptation. The Navajo Nation PRAs relied on phone calls and mail to deliver the program remotely, while the Phoenix PRAs were able to incorporate more videoconferencing and e-mails. Some participants at each site

experienced COVID-19 infections or lost loved ones, although participants at the Navajo Nation sites reported more negative impacts from the pandemic than Phoenix site participants. Due to differences in local contexts, the Navajo Nation sites were approved to resume in-person data collection more than five months later than Phoenix; this forced the Navajo Nation PRAs to rely longer on fully remote data collection visits, which likely contributed to the lower rate of completed 12-month insulin measures.

Many aspects of the TTP team's experience during the COVID-19 pandemic mirror those of other clinical research studies. Eighty percent of clinical trials were either interrupted or postponed by COVID-19 (van Dorn, 2020), and there is a growing literature exploring the effects of the pandemic on research. However, while the existing literature on adapting clinical trials to COVID-19 offers a wealth of advice about what research study leadership should or should not to do (e.g., McDermott & Newman, 2020; Mitchell et al., 2020; Perez et al., 2020; Shiely et al., 2021), it provides little information about the processes by which study teams arrive at effective decisions or how they work through the challenges of implementing them. Several articles have focused on only one domain of adaptation, such as in-person data collection visits (Padala et al., 2020; Kreuger et al., 2021) or data analysis strategies (Mara & Peugh, 2020). The few articles that summarize how studies adapted across domains and lessons learned from this experience are either about hospital-based interventions, such as cancer trials (e.g., Marcum et al., 2020), or about behavioral interventions for adults (e.g., Röhr et al., 2020). We were not able to find any articles exploring COVID-19 adaptations to behavioral interventions for children or for Native populations.

This paper fills this gap in the literature. Rather than dictating what study teams ought to do in times of crisis, we have chosen to highlight the TTP team's underlying values, which guided the strategies we employed—in other words, not just *what* we did to adapt effectively, but *how and why* we did it. The lessons we present arose out of iterative discussions of key qualitative and quantitative findings and cut across the domains of interest. They represent the core principles the TTP team believes allowed us to meet the challenges of the COVID-19 pandemic.

(1) Ensure the support offered is flexible to differing needs and responsive to changes over time

Everyone involved in a research study, including participants and staff, needs clear, consistent, and trust-based communication in times of crisis and uncertainty. There is no one-size-fits-all approach; effective support will look different for different people and must be able to adapt to changing circumstances.

We found that participants needed flexibility in their modes of communication, their schedules, and their opportunities to engage with program content. Keeping participants up to date on how the study was adapting and how those changes would impact them was particularly important. This lesson aligns with results from two recent systematic reviews that showed building participant-researcher trust, improving participant understanding of the study's purpose and components, and employing personalized, continuous contact are all effective retention strategies (Wong et al., 2021; Nicholson et al., 2015). In addition, in their recommendations for clinical trial adaptation during COVID-19, McDermott and Newman (2020) argue that "Participants should be informed of necessary changes in protocol and how this may affect the risk associated with study participation. For many randomized trials, communication from research staff is likely to help protect against dropout or nonadherence by reassuring participants that their trial involvement remains important, even during the pandemic" (p. 2135). The TTP team found that the most essential factor in all communications was providing a clear set of options and allowing participants to choose for themselves if and how to engage.

We also learned that managers must support PRAs across their spectrum of need by offering what material, technological, structural, and interpersonal help they can within the professional and financial limits of the study. This includes managers asking PRAs what they need, repeatedly and without judgment. In any crisis, we encourage PRAs to communicate with participants, and managers to communicate with PRAs, from a place of curiosity and empathy. Providing such support is key to enabling the study team in delivering the program and collecting data with fidelity and to enabling participants to fully engage in these study activities.

(2) Adapt collaboratively and iteratively while remaining rooted in community

Implementation of a research study always involves some form of adaptation; crises simply place a spotlight on this process. Carefully planning and documenting adaptations helps ensure they are effective, allows for analyses that assess how the adaptations impacted study outcomes, and supports planning for re-implementation of successful interventions in new settings (Bauer & Kirchner, 2020). When adapting study materials or processes, we recommend that research teams slow down and think creatively and collaboratively about each decision point. In the midst of a crisis it can feel like action is needed right away, but the TTP team found that workable adaptations developed only after several group planning sessions, pilot testing, and readjustment. We also found that sometimes the best adaptations were those that already existed within the study (e.g.,

TTP's make-up session method, which became the basis of remote program delivery), while others required new ideas. Studies at the same site or center may also learn from one another: for example, at the Phoenix site TTP was approved to begin in-person data collection visits before many other studies in their shared clinic space, which made the TTP PRAs role models and sources of key knowledge for staff on other studies.

Above all, adaptation should be guided by community. The centrality of community in Native health research is well established. As Whitesell at al. (2018) explain, interventions must be tailored to cultural and community context to ensure the study's rigor and outcomes. While many have written about the importance of community and culturally based intervention development at the start of a study (e.g., see Dickerson et al., 2020; Walters et al., 2020), community-based adaptation mid-study is less discussed. Jernigan et al. (2020) recently argued that we need more dissemination of study implementation strategies, including adaptation, in Native communities to ensure the scaling up and sustainment of successful interventions.

Making community-centered decisions requires incorporating information from outside the research team by seeking guidance from tribal and state authorities, community organizations, and other local sources. Managers and investigators, especially those who are not on site, may need to rely on PRAs to help identify and share pertinent safety updates, as well as to "read" the status of their community. What this process looks like in one tribal nation will differ from another, which will differ in turn from urban Native communities. Once information is gathered, additional time and effort are needed to apply it to study decisions and to resolve conflicts among different communities and institutions. TTP's COVID-19 timeline (Figure 3) illustrates our experience of this interplay between community context and study adaptation. Despite the pandemic-era popularity of the phrase "we are all in the same boat," in a multi-site team, different team members will likely be in different boats, even as they face the same storm. Some communities will be more impacted than others at various times and will have different resources to respond with. Equality of response is typically not the answer; instead, we recommend using an equity lens to adapt to each community's circumstances.

(3) Recognize that relationships are the foundation of research

The essential role of relationship in research has been explored at length by numerous Native researchers. For example, Wilson (2008) explains the concept of relational accountability by observing that researchers "are accountable to ourselves, the community, our environment or

cosmos as a whole, and also to the idea or topics that we are researching. We have all of these relationships that we need to uphold" (p. 106). To this list we would add the relationships that researchers, both Native and non-Native, have with one another as they work toward shared aims. These relationships are essential for making sound decisions and implementing those decisions effectively under challenging circumstances.

We recommend that research teams think critically and speak openly about who is giving input into which decisions across all levels of the study. High-level changes to study design always require investigator leadership. However, detail-oriented adaptations must be developed with PRA input or they are unlikely to be implemented with fidelity. In all cases, when collaboration takes place around a proposed change everyone should be clear on who is empowered to make the final decision; otherwise, team members whose input is not integrated may refuse to implement the decision or may disengage from future decision-making efforts.

When conflicts around decisions arise, teams should weigh the risks and benefits from multiple perspectives. Hsu et al. (2021) stress the ethical dimensions of the research decision-making process during the COVID-19 pandemic. However, not all members of the study team may have the same perspective on what is ethical. In a participatory analysis with diverse Native stakeholders, Parker et al. (2019) found that Native health research ethics differ from the Western research ethics outlined in the Belmont Report. Yuan et al. (2014) also found that Native research ethics in urban settings may differ from those on reservations. These complexities require us to be gentle with ourselves and our teams, especially during periods of disagreement. Decisions made under uncertain circumstances are incredibly challenging and will not always bring the results we intend. We attribute much of TTP's resilience during the pandemic to our ability to prioritize listening to and learning from one another's perspectives and to remaining united in improving the health of Native communities.

CONCLUSION

In this paper we have summarized the effects of COVID-19 on the TTP study, how our team has adapted to these challenges, the outcomes of these adaptations, and how these effects, adaptations, and outcomes have compared across research sites. We considered five domains—intervention delivery, participant engagement, data collection, data analysis, and team operations—and used the results of our mixed methods triangulation analysis to derive three cross-

cutting lessons learned. Some of these lessons, such as the importance of community-based adaptations and of making space for diverse ethical viewpoints in decision-making, are perhaps most relevant to research teams working with Native populations. Other lessons, such as the need to plan for adaptations in advance and to be flexible and supportive in times of crisis, will likely resonate with public health research teams more generally. The TTP team offers these lessons not as novel ideas, recognizing that many have been written about by others before us. Rather, they represent a consolidation of resilience strategies that we hope will support the successful adaption of Native research studies both during the ongoing COVID-19 pandemic and in future crises.

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CONFLICT OF INTEREST

The authors declare that they have no conflict of interests.

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The project manager and data manager proposed the design of this manuscript, gathered qualitative data, conducted quantitative and qualitative analyses, wrote and edited the paper, and coordinated collaborations across the study team. The PRAs collected quantitative data, provided qualitative data, and contributed to multiple rounds of editing to ensure their perspectives were being accurately portrayed and that the lessons learned resonated with their experiences. The investigators approved the approach to the manuscript and contributed to the writing and editing process.