THE IMPLEMENTATION OF SUPPORT CALLS IN A PILOT CHILDHOOD OBESITY INTERVENTION

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ABSTRACT

Low health literacy in parents has been linked to increased obesity risk for their children. When providing information to patients with low health literacy, teach-back (TB) and teach-to-goal (TTG) methods are recommended, but no studies have examined the degree to which TB/TTG strategies can be implemented with fidelity in community-based programs. A study was conducted to determine if type of delivery staff (community or research) is related to implementation fidelity; the degree to which TB/TTG methods are necessary for parent/caregiver understanding of childhood obesity learning objectives; and if baseline parent/caregiver health literacy level is related to support call response. Ninety-four families with overweight/obese children aged 8-12 years were enrolled in a pilot childhood obesity intervention that included 6 bi-weekly parent/caregiver support calls integrating TB/TTG methods into a 5 A's approach. Research partners (n=2) delivered all calls in Wave 1. During Waves 2 and 3, community staff (n=5) delivered a majority of calls with training and support from research staff.). Average completion rate across calls was 62% and did not differ according to participant health literacy level. Community partners were more likely than research partners to complete calls with participants (68% versus 57%), but this trend was not significant. Both research and community partners adhered to call scripts with high fidelity (97% versus 98%). A significant main effect of health literacy level on TB/TTG performance was found for Call 1 and Call 3 during Wave 1 and for Call 1 during Waves 2 and 3 of iChoose ($p<0.05$, 0.01, and 0.05). An interaction effect of health literacy level and question number was found for Call 3 during Wave 1 only ($p<0.05$). For all calls in which TB/TTG performance differed significantly by health literacy level, participants with adequate health literacy were found to have better performance. Following the program, participants expressed they felt satisfied and comfortable with follow-up calls (9.1 (2.0) and 9.5 (1.2) on a 10-point scale), while agreeing that calls helped improve their eating and PA habits (8.1 (2.6) and 7.5 (2.7)) and helped them learn class material better (8.1 (2.7)). Trained community partners were able to deliver the same support call content with similarly high fidelity, completion, and acceptability. Although participant baseline health literacy level had less impact on the need for TB/TTG and on program perception than we anticipated, our findings open up different possibilities to utilize these strategies while using precious resources more efficiently.

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ABSTRACT (PUBLIC)

Low health literacy – meaning a limited capacity to access and understand basic health information that is needed to make suitable health decisions – has been linked to a plethora of poor health behaviors and outcomes, including increased obesity risk for the children of low health literate parents. When sharing information to patients with low health literacy, teach-back (TB) and teach-to-goal (TTG) methods are recommended in which health care professionals ask patients to repeat instructions or explain key concepts using their own words and then re-instruct patients as needed until they master these concepts. No studies thus far have examined the degree to which TB/TTG strategies can be implemented with fidelity – meaning adherence to protocol and competence in delivery – in community-based programs. A study was conducted to determine if type of delivery staff (community or research) is related to implementation fidelity; the degree to which TB/TTG methods are necessary for parent/caregiver understanding of learning objectives in a program to improve health-related behaviors; and if baseline parent/caregiver health literacy level is related to support call response. Ninety-four families with overweight/obese children aged 8-12 years were enrolled in a pilot childhood obesity intervention that included 6 bi-weekly parent/caregiver support calls integrating TB/TTG methods into an evidenced-based 5 A's approach for behavioral change. Research partners delivered all calls in Wave 1 of the pilot trial, while community staff delivered a majority of calls during Waves 2 and 3 with ongoing training and support from research staff. Average completion rate across calls was 62% and did not differ according to participant health literacy level. Community partners were more likely than research partners to complete calls with participants (68% versus 57%), but this difference was not significant (it may have been due to chance). Both research and community partners followed guided call scripts with high fidelity. The health literacy level of participants at the start of the program was associated with TB/TTG performance during calls, but this effect was limited to only a few calls. In all of these instances, participants with the higher level of health literacy (adequate) were found to have better TB/TTG performance. Following the program, participants expressed they felt satisfied and comfortable with follow-up calls, while agreeing that calls helped improve their eating and physical activity habits and helped them learn class material better. Trained community partners were able to deliver the same support call content with similarly high fidelity, completion, and acceptability. Although participant baseline health literacy level had less impact on the need for TB/TTG and on program perception than we anticipated, our findings open up different possibilities to utilize these strategies while using precious resources more efficiently.

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LITERATURE REVIEW

Childhood Obesity and CBPR

Prevalence of childhood obesity has risen dramatically over the past 30 years, more than doubling among children and quadrupling among adolescents.[1-3] It was recently estimated that more than one-third of US children and adolescents were overweight or obese.[1,2] Childhood obesity is known to cause health problems which include asthma and musculoskeletal impairment.[4] Similar to findings in adults, obesity in children has been linked to increased risk for pre-diabetes, type 2 diabetes mellitus, obstructive sleep apnea, dyslipidemia, hypertension, cardiovascular disease, and depression.[5,6] There is also evidence to suggest greater utilization of health care resources, including mental health care, by obese children.[7] Direct medical costs associated with childhood obesity in the US are estimated to total $14.1 billion per year.[8] Moreover, overweight children are highly likely to become overweight or obese adults who will continue to be at higher risk for a large number of serious comorbidities.[4,9] Obesity in adulthood is associated with increased spending on health care and decreased life expectancy.[6,10,11] In light of this evidence, childhood obesity is clearly a public health priority area. Innovative intervention strategies are urgently needed and, if effective, are likely to provide significant health as well as economic benefits.

While the incidence of childhood obesity is high across societal groups, racial/ethnic minorities and low-income communities are disproportionately burdened compared to other groups.[12,13] Thus, the development of strategies that effectively address obesity in minority and low-income populations is considered a national research priority.[14,15] Especially for these high-risk communities, it is critical for obesity interventions to be culturally relevant and tailored to

the needs of the target population in order to improve health outcomes and reduce disparities.[16] Health promotion efforts must consider multiple levels of influence, including individual knowledge and family as well as community settings. Previous research has shown that family and community involvement are crucial elements of child obesity intervention or prevention programs, especially in rural settings.[4,17,18] Community-based participatory research (CBPR) is considered the "gold standard" for engaging community members in intervention research and delivery.[19-22] The CBPR approach calls for equitable community-academic partnership and community participation during all phases of the research process from conception to dissemination. This allows the unique knowledge and resources of both community and research partners to be applied synergistically toward shared goals of improving health outcomes and inequalities. CBPR also benefits communities through an emphasis on strengthening local capacity and sustainability. The National Institutes of Health (NIH) recommends CBPR as an "essential tool" for action-oriented community health research with the potential to reduce health disparities and enhance study relevance, validity, effectiveness, cultural sensitivity, and translation into practice.[22,23]

The CBPR approach has been applied in a number of studies focusing on childhood overweight and obesity in the US. However, a limited portion of these have reported on primary outcomes of child weight, body mass index z-score (BMIz), or prevalence of overweight and obesity. Even fewer have described longer-term outcomes. Nonetheless, promising results can be found among the studies that have reported on key outcomes of interest.[24-32]

Shape Up Somerville (SUS) was a 2-year non-randomized controlled trial (NRCT) carried out in 3 culturally diverse socio-demographically-matched cities in Massachusetts to evaluate the impact of a CBPR intervention on obesity in young children.[24,25] A total of 1,028

public school children in grades 1 to 3 participated (335 in the intervention community). Intervention components focused on increasing the availability of healthy foods and PA opportunities within diverse school, household, and community environments. These researchers did not provide details regarding the theoretical underpinnings of the intervention. Across the 2 years of the study, SUS significantly reduced BMIz (0.06) and doubled the rate of overweight and obesity remission in intervention children compared to control children. Prevalence of overweight and obesity was nearly 30% lower among intervention versus control children. To promote sustainability, researchers also guided the intervention community in obtaining independent funding and in transferring intervention work to community partners. These results show that use of a CBPR approach to increase the availability of healthy food and PA options can help to prevent and treat childhood obesity within a culturally diverse community.

Healthy Living Cambridge Kids (HLCK) was another Massachusetts-based multi-component CBPR intervention. Guided by the socio-ecological model in conjunction with CBPR principles, it targeted changes at the individual, family, school, and community levels to promote healthy weight and PA in children.[26] This study used a longitudinal design to evaluate the effect of the 3-year intervention on the weight status and fitness levels of a cohort of 1,858 children in kindergarten through 5th grade. Participants were diverse with respect to race, ethnicity, and household income level (37% black, 14% Hispanic, and 43% low-income). Components of the intervention ranged from physical education (PE) and food service reforms to family and community outreach. Follow-up data revealed modest but significant reductions to BMIz (0.04) and prevalence of obesity (2.2%) among participants. Prevalence of obesity decreased among all race/ethnicity groups and income levels at follow-up. However, black, Hispanic, and lower-

income participants were more likely to be obese at baseline and follow-up. Further tailoring of strategies may be needed to improve these disparities.

Two participatory studies adapted an evidence-based elementary school healthy eating and PA program, the Coordinated Approach To Child Health (CATCH), to help address childhood obesity within ethnically diverse, low-income Texas communities. In the first, researchers worked closely with a local non-profit foundation to implement a comprehensive community health initiative in the El Paso, Texas region.[27,33] Although this initiative did not explicitly use a CBPR approach, it was driven by and tailored to community needs and involved extensive community contributions. The CATCH program—guided by elements from Rogers' diffusion theory, social cognitive theory, and social marketing—was a key component of this initiative.[34-37] Participating in CATCH was found to slow but not stop the rise in obesity and overweight among 3rd grade children. Although overweight and obesity prevalence increased significantly for participants in all schools as they progressed from 3rd to 5th grade, the increase was 11% less for girls and 8% less for boys in intervention versus control schools.[27] Furthermore, the regional obesity rate for 4th graders dropped 7% in the 2.5 years after this community health initiative was introduced.[33] Although this prevalence data is not sufficient to support strong causal inferences, overall results suggest that a multi-component community-based intervention can help to combat childhood obesity within a high-risk community.

The Travis County CATCH Trial also adapted the CATCH program to examine whether the addition of community involvement guided by CBPR principles, the socio-ecological model, and social cognitive theory could further enhance program effectiveness.[28] During the 4-year non-randomized controlled trial (NRCT), 15 predominantly Hispanic low-income elementary schools received the intervention (CATCH program plus community involvement) while 15

matched schools received the control (CATCH program only). One-year results revealed a significant 8.3% decrease in overweight and obesity prevalence among 4th grade students from intervention schools. This improvement was also significantly greater than the 1.3% decrease reported from control schools. These findings provide limited evidence that the incorporation of community involvement can enhance the effectiveness of a childhood obesity intervention for low-income communities.

Foster and colleagues conducted a cluster-randomized trial to evaluate the effects of a community-originated and delivered School Nutrition Policy Initiative (SNPI) on preventing childhood overweight and obesity.[29] This intervention was adapted from the Centers for Disease Control and Prevention (CDC) Guidelines to Promote Lifelong Healthy Eating and Physical Activity to meet local needs.[38] Key components included school environment self-assessments, nutrition education, nutrition policy, parent outreach, and social marketing. Participants were 4th to 6th graders (n = 1,349) from 10 urban public schools in Philadelphia, Pennsylvania. Schools were matched based on size and food service, then randomized to the intervention or control condition.

After 2 years, results showed that intervention students were 33% less likely to become overweight than control students. Prevalence of overweight was also significantly lower in intervention schools. The intervention's effect on overweight prevalence was especially pronounced for black students, such that black students in intervention schools were 41% less likely to be overweight at follow-up than those in control schools. However, neither incidence nor prevalence of obesity differed by treatment. The intervention also resulted in significant improvements to sedentary behavior and weekly television (TV) viewing compared to the

control group. Similar to the El Paso CATCH study, the SNPI intervention was found to slow but not stop the rise in childhood overweight and obesity.

Although a majority of the above studies targeted diverse communities, none of them sought to address childhood obesity in a specific minority population. Choudhry and colleagues conducted a pilot study to evaluate whether Power-Up, a 14-week after-school program, could reduce obesity risk in black children.[30] This study used a CBPR approach to actively engage community members in the study design, delivery, and evaluation. The theoretical framework for this intervention was a conceptual model based on key concepts from multiple behavior change theories, including the theory of planned behavior, health belief model, social learning theory, and ecological model.[39] Power-Up was delivered within the after-school program of an all-black community school with predominantly low-income students. The program centered on 14 weekly after-school children's nutrition and PA sessions that incorporated interactive activities such as recipe development. Topics from these sessions were also reviewed with parents during weekly parent group sessions. Lastly, environmental changes such making after-school snacks healthier were made at the school.

Forty black children (aged 5 to 12 years) and 28 parents participated in the Power-Up program. Follow-up data showed significant reductions to BMIz (0.24) among participating children, with greater benefit to those who were overweight at baseline than to those who were obese. Prevalence of overweight and obesity decreased for girls only from 52% to 46%. Researchers felt that the CBPR approach was central to the successful integration of Power Up into a community after-school program and to enhancing its sustainability.

Lastly, 2 pilot studies aimed to address obesity in younger children by targeting low-income Head Start families with preschool-aged children. Eat Healthy, Stay Active! was a 6-

month multisite literacy-sensitive educational program that promoted healthy eating and PA among Head Start staff, parents, and preschoolers.[31] Consistent with CBPR principles, researchers engaged community partners in the design and implementation of this program. Additional theoretical foundations for the program included social learning theory and evidence-based theories of communication, empowerment, and engagement. Eat Healthy, Stay Active! was pilot tested using a pre-post design in collaboration with 6 Head Start agencies with 75 sites in 5 states. Average BMI and obesity prevalence decreased significantly from baseline to follow-up for all participant groups. Prevalence of obesity fell by 6.7% and 9.9% among parent and child participants, respectively. BMI decreased by 1.2 and 0.4 among parent and child participants, respectively, and weight changes in children correlated with those in parents. Confidence in these results would have been strengthened by the use of a concurrent control group and intent-to-treat analysis in light of the high attrition rate.

Davison and colleagues also conducted a pilot study with low-income Head Start families. They sought to promote parent engagement by empowering parents as equal partners in developing, testing, and evaluating a family-focused childhood obesity intervention for Head Start families with children aged 2 to 5 years.[32] The design for this intervention was primarily guided by the Family-centered Action Model of Intervention Layout and Implementation with underpinnings in nutrition, child development, and public health.[40] The central component of this 6-month intervention was a 6-week parent-led education program that focused on improving communication, social networking, advocacy, media literacy, and conflict resolution skills in parents. Additional components included a health communication campaign to increase awareness and accurate understanding of childhood obesity; improvements to letters to parents reporting on child BMI; and informal family nutrition counseling.

In total, 423 preschoolers and 154 families from 5 Head Start sites participated in this pilot study. Follow-up results analyzed using intent-to-treat analyses revealed a significant 3.9% decrease in child obesity prevalence as well as a nonsignificant downward trend in BMIz. Significant improvements to dietary quality, PA, and TV viewing were also reported in child participants. Similar to the previous study, the strength of causal inferences that can be drawn from these results is limited without the use of a concurrent control. Nonetheless, both studies offer promising evidence supporting the feasibility and effectiveness of integrating childhood obesity prevention programming into existing community services for vulnerable families.

To the best of our knowledge, only the 8 studies described above have reported on key outcomes of interest—child weight, BMIz, or overweight and obesity prevalence—for community participatory childhood obesity interventions in the US. All of them reported significant improvements to at least one key outcome of interest following intervention. However, effect sizes were generally modest. The use of a participatory approach was reported to help increase community capacity, tailor interventions to better meet community needs, ease integration of intervention components into existing community infrastructure, and promote program sustainability.[24,25,27,30] One study even produced limited evidence that use of CBPR can enhance the effectiveness of an intervention to reduce the prevalence of child overweight and obesity.[28]

Consistent with recommendations to use CBPR for health disparities, all of these studies delivered interventions to racially/ethnically diverse and/or low socioeconomic communities. Based on a limited number of studies that reported on intervention effectiveness by race/ethnicity and income level, additional or modified strategies may be needed to significantly reduce these disparities.[26] None of these studies focused on overweight or obese children exclusively, but

results from one study suggest that a tailored intervention may be needed at higher BMI percentiles.[29]

The majority of these studies used a school-centered approach, though many combined this with various additional strategies outside of school. While school-based interventions may be convenient, there is evidence to support increased focus of childhood obesity intervention research toward other settings. Children consume a vast majority of their total calories outside of school settings, including approximately 66% inside of their homes.[41] Furthermore, they spend more than half of their waking hours away from school and may have greater choice over whether to be physically active during this time.[17] The impact of school-based interventions may also be blunted by conflicting outside influences.[17] Future CBPR research concerning childhood obesity should therefore place more emphasis on community-based and/or family-centered interventions in addition to school-centered ones.

The wide variety of study settings, designs, and target populations used in these 8 studies makes it difficult to draw strong, specific conclusions across all of them. Although customization of research efforts to community needs is one of the strengths of CBPR, some standardization of reported methods and outcome measures would greatly facilitate meaningful comparisons of CBPR studies. Nevertheless, initial outcomes from a limited number of studies suggest that community-based participatory interventions can produce significant improvements that promote healthy childhood weight status in diverse communities.

Caregiver Health Literacy and Low Health Literacy Strategies

Health literacy, commonly defined as the extent to which an individual has "the capacity to obtain, process, and understand basic health information needed to make appropriate health decisions," is estimated to be low for about 87 million (36%) adults in the United States,

meaning that a significant proportion of Americans has trouble understanding and following health messages.[42,43] While such issues are widespread, poor health literacy has been found to be more prevalent among rural and low socioeconomic populations.[44,45] Those with low health literacy (LHL) are less likely to be well-informed about their chronic diseases, less likely to have sufficient self-management skills, and more likely to make mistakes taking medications.[46] A growing body of research strongly links LHL to a variety of adverse health outcomes.[47-50] In fact, health literacy level has been found to be a better predictor of health status than age, ethnicity, employment, income, or education level.[51] In the context of nutrition and obesity, LHL has been associated with problems understanding food labels and portion sizes and with higher body mass index (BMI) in adults.[52,53]

Furthermore, the impact of low health literacy on health outcomes likely extends beyond the individual. Nearly 30% of US parents are estimated to have LHL, and there is evidence that children of LHL parents are more likely to have unmet health care needs, be uninsured, and be taken to the emergency department (ED) for nonurgent reasons.[54-58] Studies have linked low parent health literacy to poor knowledge and comprehension of child health information; poor family health behaviors; and poor child health outcomes.[54,59,60] For example, evidence suggests that parents with LHL are less able to properly prepare infant formula, recognize correct portion sizes, and understand food labels and medication instructions.[54,61] A cross-sectional analysis also found associations between certain "obesogenic" infant care behaviors—such as watching television while feeding—and low parent health literacy.[62] A different study found that parents with LHL were twice as likely to misidentify their overweight children as normal or underweight.[54,63] Limited research has demonstrated a link between LHL in parents and increased obesity risk in children aged 7 to 11 years as well as worse glycemic control in type 1

diabetic children.[61,64-66] Overall, parents with LHL are 1.2 to 4 times more likely than parents with adequate health literacy to display negative parenting and child preventative care behaviors.[61] A systematic review on literacy and child health thus concluded that any effective framework for improving child health services should include addressing health literacy issues.[61] The same review also stressed that child health research needs to extend beyond clinical settings to include community-based participatory research.

There are a number of strategies to improve written and verbal communications for individuals with low health literacy. These include enhancing the readability of written materials, limiting the number of concepts introduced at one time, supporting textual instructions with pictures and/or video, and utilizing the teach-back method during patient interactions.[67] Health literacy interventions targeting parents and caregivers remain limited with only 17 studies identified thus far.[31,68-83] Participants were randomly assigned to treatment groups in 7 out of the 17 studies. Interventions were carried out in clinical and community settings and targeted a variety of outcomes including comprehension and recall of health-related information as well as health care utilization. Evidence from 10 studies showed that the application of clear communication strategies—including plain language, pictographs, and/or multimedia—for health education improved health knowledge-related outcomes.[59,68-77] Two of these reported improvements only in parents with low literacy, while another two reported improvements only in parents with higher literacy.[68-70,72] Four interventions used a low literacy self-help booklet and/or verbal parent instruction to target pediatric emergency department (ED) utilization, and all of these resulted in significant reductions to ED use.[78-81] Results from two home visitation interventions also demonstrate that helping vulnerable parents build reflective skills can be an effective strategy for building up their health literacy.[82,83] Lastly, a 6-month health literacy-

sensitive educational intervention was implemented at 6 Head Start programs to improve nutrition and physical activity among parents, staff, and preschool-age children.[31] This intervention brought about significant reductions to obesity rate and BMI for both adults and children.[31]

In sum, the current body of parent and caregiver studies suggests that interventions employing health literacy strategies have a positive impact on health-related knowledge, behaviors, and outcomes. Yet there are notable gaps in the literature that call for additional studies to investigate the longer-term outcomes of using literacy-sensitive strategies in more diverse, low literate populations.

One health literacy strategy in particular, the teach-back (TB) method, is frequently endorsed for widespread use by organizations such as the American Medical Association to address challenges in health communication.[84-87] To utilize this strategy, health care professionals ask participants to repeat instructions or explain key concepts using their own words.[84,88] Teach-back can be performed to assess participant comprehension as well as to clarify and reinforce key messages. There is reason to believe that patients of all races, ages, and education levels could benefit from teach-back.[87] The related teach-to-goal (TTG) approach takes this strategy a step further by calling for multiple rounds of TB instruction to be repeated until participants achieve their learning goals.[89-91]

The usefulness of this approach is highlighted by a descriptive study conducted by Sudore and colleagues which applied the TTG method to an informed consent process, then evaluated the number of TB rounds needed to achieve comprehension for 204 ethnically diverse older participants.[92] Only 28% of participants mastered the material in the first round. Moreover, TTG performance was strongly correlated with literacy level such that participants with

inadequate literacy were much more likely to need multiple rounds of TB than participants with adequate literacy to achieve comprehension (88.9% and 63.9%, respectively). These findings suggest that increased adoption of the TTG approach may help to reduce health disparities among low literate and low health literate populations as well as to improve the effectiveness of health communications overall.

The existing literature shows that teach-back strategies can be beneficial toward the promotion of a variety of health behaviors, including reducing medication dosing errors and improving medication adherence for children when TB was administered to their caregivers.[71,89-91,93-95] However, the literature remains limited with respect to the incorporation of TB/TTG strategies into other avenues of health communication such as telephone support and into health-related behavioral interventions outside of clinical settings. Only 6 studies have been identified that assess the use of health-related interventions including a TB or TTG call component, and their findings are described below.

DeWalt and colleagues developed a 12-month intervention program to provide practical self-management education to help HF patients manage fluid volume status.[96] The intervention was designed for low literate patients and utilized educational materials written at a 3rd-grade level as well as a TB approach to patient education that focused on daily weight measurement, self-adjustment of medication dosage, and HF symptom identification and response. Patients also received follow-up calls from a clinician to reinforce prior training and build up motivation. During calls, patients were asked to describe their self-management practices and received constructive feedback.

In this trial, 127 patients (41% with low literacy skills) were randomized to the intervention or standard care. Patients who received the intervention had lower hospitalization

and mortality rates and this difference was greater for low literate patients, but these findings were not statistically significant.[96] However, HF-related knowledge, self-efficacy (SE), and daily weight measurement did improve significantly more in the intervention group than in the control group. HF-related quality of life did not differ significantly between groups. These findings suggest that use of the TB approach for in-person and telephone instruction can increase knowledge, SE, and self-care behaviors related to HF.

Another 12-month randomized controlled trial (RCT), also led by DeWalt, compared the effectiveness of a single versus multiple session literacy-sensitive self-care training for 605 HF patients.[93] The mean age of participating patients was 61 years, and 37% had low literacy.[90] Single session patients received a 1-hour educational session at the time of hospital discharge. Multisession patients received the same 1-hour session plus ongoing support calls that included reinforcement of key program concepts, assessment of patient knowledge and behaviors, and provision of feedback and motivation. One month into the program, a TTG approach was integrated into the support calls such that educators would call multisession patients biweekly until they achieved mastery of all key content.

These patients received a mean of 14.2 ± 4.8 calls during the trial with a mean duration of 12.0 ± 4.3 minutes each.[93] Neither all-cause nor HF-related hospitalization and death rates differed by intervention group. However, it appears that patients with low literacy benefited significantly more from the intensive multisession intervention with respect to hospitalization rate than patients with higher literacy. Thus, a more intensive self-care training incorporating TB/TTG support calls may be well-suited to patients with lower literacy.

In a study based on the same RCT, Baker and colleagues compared the effects of the single versus multisession intervention on the knowledge, self-care behaviors, and HF-related

quality of life (HFQOL) of HF patients.[90] The TTG multisession intervention produced greater knowledge, notably better achievement of self-care goals, greater self-efficacy, and higher HFQOL than the single session intervention. These results further support the use of TB and TTG approaches for health communication and promotion.

In a recent prospective cohort study also involving HF patients, White and colleagues investigated the extent to which patients educated on HF self-care using TB and TTG approaches retained that information as well as the potential association between TB performance and hospital readmission rates.[97] Participants consisted of 276 elderly HF patients hospitalized over a 13-month period with a mean age of 80 years. While hospitalized, each participating patient received a single educational session from 2 registered nurse coordinators who employed TB and TTG approaches to instruct patients on key topics related to HF self-care. These included utilization of diuretic pills, fluid and sodium restrictions, daily weight measurements, adherence to medical therapies, and symptoms that would warrant calling a health care provider. Family members and caregivers were included in this education when willing and able to participate. Patient learning was assessed using 4 TB questions at the end of the session. Those who answered any question incorrectly received additional instruction until they mastered the concept(s). Patients were also given handouts to reinforce this educational content and scales to weigh themselves on at home if they did not already have one.

All patients received a follow-up telephone call within 7 days of hospital discharge in which they were asked the same TB questions to assess recall of the in-hospital instructional content. Although the primary purpose of these calls was to assess retention of learning, a TTG approach was once again applied such that patients answering any question incorrectly were given additional instruction until they understood the concept(s). The length of in-hospital

educational sessions varied from 15 to 120 minutes with patients receiving 34 minutes of instruction on average. Patients answered at least 3 out of 4 self-care TB questions correctly 84.4% of the time prior to discharge and 77.1% of the time during follow-up calls. The length of in-hospital educational sessions was significantly and positively correlated with TB performance.[97] Patients who performed well on TB questions also had lower all-cause and HF-specific 30-day hospital readmission rates. Although these findings were not statistically significant, the negative association between TB performance and HF-specific 30-day readmission rates showed a trend toward significance.

The work of White and colleagues illustrates the effectiveness of using TB to instruct patients on as well as to assess their comprehension of health-related behavioral guidelines. These results also suggest that investing more time into TB-based instruction may result in greater retention. Since it is difficult to infer causality based on this study design, future research into the impact of TB education on hospital readmissions should use an RCT design comparing TB education to standard care.

White and colleagues also conducted a pilot study with the goals of improving self-care behavior, decreasing length of stay (LOS), and reducing the 30-day readmission rate among HF patients by implementing a revised model of care in an inpatient medical-surgical nursing unit.[98] The goal of this model was to apply a multidisciplinary approach to enhance patient education. This included a newly created evidence-based physician order set and clinical pathway for nurses to follow during hospitalization. This model also encompassed longitudinal case management including follow-up calls within 48 hours after hospital discharge.

As part of this new HF education clinical pathway, nurses were taught to use the TB method and then applied it to instructing HF patients on medications, diet, daily weights,

warning signs, exercise, and HF symptoms for the 4 days following initiation of the clinical pathway. Discharged patients received a call within 48 hours to evaluate their retention of HF educational content and adherence to recommended home regimens. Patients who required further education to master any of the topics from the clinical pathway were provided more instruction over the telephone. Additional calls were made to reassess the understanding of these patients.

Fifty-nine HF patients were evaluated over a 2-month period. Four of these patients needed to have one or more educational topics reinforced and thus received weekly phone calls for 2 weeks. The study found a significant reduction in readmission rate from 23.1% to 12.9% as well as nonsignificant decreases in HF LOS.[98] This study suggests that a patient education-centered model of care incorporating TB and TTG methods into evidence-based instruction can improve readmission rates, LOS, and self-care among HF patients.

Lastly, a small pilot study conducted by Zipp and colleagues investigated the effect of an intensive carbohydrate counting educational intervention on diabetes control in adult type 2 diabetes mellitus patients.[99] Participants consisted of 6 patients who took part in standard care diabetes nutrition education followed by additional in-person education about carbohydrate counting. This initiated a 3-month intervention during which patients kept detailed daily records of blood glucose values, carbohydrates consumed, and energy levels. Regular telephone calls and office visits were used to reinforce concepts, monitor compliance and well-being, and collect records. Researchers conducted weekly telephone calls with each patient that included review of carbohydrate counting concepts and assessment of comprehension via the TB method. Call frequency was reduced to every other week after the first month. Diabetes control was assessed by measuring hemoglobin A1c (HbA1c); blood glucose; lipid profile; and sense of well-being.

Out of 6 enrolled patients, only 4 completed the intervention. Although marginal improvements—primarily to HbA1c—were reported, a number of factors hinder meaningful interpretation of these results.[99] The study design failed to account for many potential confounders, including one patient's prolonged hospitalization between follow-up assessments. The already small sample size of this study was also weakened further by low and inconsistent patient participation and high attrition.

However, the patients who did engage submitted strong positive feedback that they enjoyed the individual teaching, support, and follow-up provided by the telephone calls. This data offers limited support for the acceptability of telephone support using TB methods within an educational intervention for health promotion. Follow-up research using stronger study design is needed to establish and enhance the effectiveness of this intervention and to build on the currently limited literature regarding participant perceptions of TB. At the very least, future studies should employ a larger sample size, a standard care control group, patient randomization, and more detailed reporting on patient characteristics.

The current body of literature remains limited with respect to the integration of TB and TTG strategies into other avenues of health communication such as telephone support and into health-related behavioral interventions outside of clinical settings. Of the studies currently identified as assessing the use of TB and TTG calls in health-related interventions, a large majority (5 out of 6 studies) focused on heart failure (HF) as the health condition of interest.[90,93,96-98] The one remaining study focused on diabetes education.[99] Nevertheless, the evidence from these studies suggests that the incorporation of TB methods into face-to-face and telephone health communications may support a variety of positive intervention outcomes, including increased health-related knowledge, self-efficacy, self-care behaviors, and quality of

life as well as reduced hospital length of stay and readmission rates. Further research utilizing rigorous study design is needed to confirm the acceptability and effectiveness of TB and TTG calls in a wider range of patient populations and health-related interventions.

Implementation Science and Training Strategies

Growing evidence suggests that health promotion strategies shown to be efficacious in controlled research settings may not produce the same benefits in more realistic settings.[100,101] In order to achieve meaningful public health impact, community interventions must demonstrate robust effects in participants diverse across race/ethnicity, socio-economic status (SES), literacy and health literacy, and motivation levels. Further, they must remain effective when delivered by community staff—who often have varying levels of expertise, limited material resources, and competing time commitments—rather than by research staff. The latter is crucial since it will be up to community staff to sustain interventions over time. The field of implementation science has arisen to address such challenges. Implementation research strives to identify the best methods for disseminating and sustaining evidence-based practices within community settings.[102]

The literature shows that even a shift in delivery staff can significantly impact behavioral intervention outcomes. For example, Stevens and colleagues found that a brief smoking cessation intervention led to significant benefits when delivered by experienced smoking cessation counselors but not when delivered by hospital therapists in the same setting.[103] Less consistent protocol implementation by hospital therapists appeared to account for at least part of this discrepancy. Findings such as this illustrate the importance of implementation fidelity, or the extent to which intervention components are delivered as intended.[100] This includes not only adherence to protocol but also competence in delivering specific intervention components.[100] High fidelity may help preserve the behavioral change mechanisms that produce intervention

benefits.[104] Low fidelity, on the other hand, likely contributes to diminished results when evidence-based treatments are applied to real-world settings.[105,106] Consequently, implementation fidelity is often considered essential to the successful translation of evidence-based health promotion approaches to practice.[107,108]

Despite increasing awareness of the importance of implementation fidelity, reporting of fidelity remains limited across many fields of research.[109] In fact, an evaluation of health behavior intervention articles published in 5 major journals from 1990 to 2000 found that only 27% assessed protocol adherence and 54% did not use any fidelity measures.[110] This lack of fidelity assessment and reporting in research is problematic as it allows variations in fidelity to confound intervention results. Evaluation of implementation fidelity can also serve other purposes. Low fidelity scores in specific areas of implementation may help to highlight setting-specific challenges and inform future adaptations for local implementation.[111] Dependent on the research design, fidelity scores can even be leveraged to resolve problems and thereby improve delivery quality within the same study.[112] Meta-analyses of intervention research indicate that monitoring of fidelity as well as higher fidelity scores are associated with greater improvements to outcome variables.[108]

Implementation approaches that promote high fidelity are needed to facilitate effective dissemination of evidence-based practices. Current literature indicates that community collaboration and multi-component training procedures that incorporate active learning strategies and account for contextual factors can promote high quality of delivery.[113] There is also growing evidence that consultation or ongoing support following initial training can enhance training as well as intervention outcomes.[114,115] While consultation is itself an active learning method, it

incorporates a variety of other active learning strategies such as modeling, role playing, self-evaluation, and performance-based feedback.[113,116]

The training and consultation literature offers preliminary support for many of these active learning strategies.[114] For example, Cross and colleagues reported that including role play as part of a suicide prevention gatekeeper training significantly improved skill levels compared to standard training.[117] Another study conducted by Edmunds and colleagues found no significant relationship between time spent on role play during group consultation sessions for cognitive-behavioral therapy (CBT) and trainee outcomes.[114] However, the authors did find that behavioral rehearsal using role play had a greater effect on CBT skill level when trainees were more involved during consultation sessions. The marginal amount of time given to behavioral rehearsals (4.71 minutes per session) and low participation rate in them (28%) may help to explain the lack of significant findings. Schoener and colleagues evaluated the effects of a 2-day motivational interviewing (MI) workshop followed by 8 group consultation sessions that included self-evaluation.[118] After undergoing training and consultation, community therapists demonstrated improved MI delivery skills and increased change talk among their clients. Lastly, Miller and colleagues conducted a randomized trial to compare the effects of 5 MI training conditions on substance abuse counselors.[119] The conditions consisted of a self-training control, a single workshop, a workshop plus feedback, the workshop plus individual coaching, and the workshop plus both feedback and coaching. All groups gained more proficiency than the self-training control group. Beyond that, the inclusion of coaching and/or feedback boosted post-training proficiency at 4-month follow-up compared to a single workshop.

In summary, successful translation of research innovations requires pragmatic training strategies that empower community staff to deliver interventions with high quality. Although

much of the current training literature relates to psychotherapy, the studies discussed above provide promising evidence of implementation strategies for training practitioners to deliver research-based, behavioral interventions in real-world settings. Further research is needed to connect specific training strategies or combinations of strategies to high fidelity and effectiveness in delivering actual interventions. Preliminary findings regarding these training strategies must also be validated and expanded upon in other areas of behavioral intervention research, including childhood obesity prevention and treatment.

The DRR, DRPHC, and iChoose program

The Dan River Region (DRR) is a federally designated medically under-served area in south central Virginia and north central North Carolina that encompasses the city of Danville as well as Pittsylvania, Henry, and Caswell Counties.[120-122] It contains a racially diverse population that is approximately 30% black.[123] The DRR is known to suffer from educational, economic, and health disparities including low levels of educational attainment, high levels of poverty (~19%), as well as high prevalence of adult obesity and type 2 diabetes mellitus (~35% and 30%, respectively).[120,121,123-126] While there is no direct data on health literacy levels in the DRR, low basic literacy levels are known to be prevalent (~6% higher than the state average).[127] Combined with the fact that this is a predominantly rural and low SES population, it can be reasonably assumed that low health literacy levels are common as well.[44,45,123,124]

Health disparities are evident among not only adults but also children in the DRR. Limited data from a local school district suggests that regional prevalence of childhood obesity may be more than double the state average (~14%).[128,129] The Dan River Partnership for a Healthy Community (DRPHC)—a community-academic partnership—was formed to address these and other regional health priorities using a CBPR and systems-based approach.[130]

Propelled by community concerns regarding the lack of nearby pediatric weight management programs, the DRPHC created the Partnering for Obesity Planning and Sustainability Community Advisory Board (POPS-CAB). This advisory board brought together regional health care, public health, parks and recreation, and academic partners. The POPS-CAB was able to secure an R24 CBPR planning grant from the National Institute on Minority Health and Health Disparities (NIH-NIMHHD) to address childhood obesity treatment in the DRR. The iChoose program was developed by the POPS-CAB as a CBPR-tailored intervention using principles from an evidence-based childhood obesity intervention, Bright Bodies, to meet regional needs.[131]

Primary Aims and Hypotheses

Aim 1: Determine if type of delivery staff (community or research) is related to support call implementation fidelity, completion, and acceptability. We hypothesized that community staff would deliver caregiver support calls with high levels of fidelity and competence comparable to research staff when community staff was provided with thorough training and ongoing support and supervision. We also hypothesized that support call completion rates and call lengths would be similar between community and research staff. Lastly, we hypothesized that caregivers called by community staff would express equally or more positive attitudes regarding the calls in post-intervention summative assessments.

Aim 2: Determine the degree to which teach-back and teach-to-goal methods are necessary for adequate and limited health literacy parents/caregivers as assessed by performance on identifying key learning objectives of the intervention. We operationalized the need of teach-back and teach-to-goal methods based on the degree to which participants required multiple opportunities to demonstrate understanding of the key learning objectives. We hypothesized that parents/caregivers would require additional opportunities to demonstrate

comprehension. We also hypothesized that parents/caregivers with limited health literacy would require these additional opportunities to a greater extent than those with adequate health literacy. Parents/caregivers who completed missed class calls received instruction on key learning objectives during the call and shortly before answering the TB/TTG questions. In contrast, those who completed follow-up calls needed to recollect what they learned during the preceding family session approximately 1 week prior to the call. Due to this difference in the amount of time allowed to pass between instruction and assessment, we hypothesized that performance on TB/TTG questions would be better for missed class calls than for follow-up calls.

Aim 3: Determine if baseline parent/caregiver health literacy level (limited or adequate) is related to support call completion and receptiveness. We hypothesized that caregivers with higher health literacy would complete more support calls and express more positive attitudes regarding the calls in post-intervention summative assessments.

Chapter 2

METHODS

Study Design and Intervention Structure

This research was a part of a larger 3-wave pilot community-based trial. The primary aim of this trial was to determine the potential reach, effectiveness (*i.e.*, changes in child BMI z-scores over a 6-month period), feasibility, and cost of the iChoose program, a 12-week family health behavior intervention for childhood obesity reduction. The POPS-CAB used a CBPR approach to collaboratively develop the iChoose program based on the principles of Bright Bodies, an evidence-based childhood obesity intervention.

The iChoose program offered the following components across 12 weeks: (1) bi-weekly 90 to 120-minute Saturday family sessions focusing on nutrition, exercise, and behavioral skills; (2) bi-weekly caregiver telephone support calls to set goals, resolve barriers, and reinforce content using TB/TTG strategies between family sessions; (3) twice-weekly 60-minute exercise sessions; (4) workbooks for both parents and children based on clear communication strategies; and (5) children's newsletters that reinforced program content and provided fun activities. To promote a high quality of implementation, lesson plans, fidelity checklists, and presentation slides were developed and used for all family sessions. All family and exercise sessions were held in Danville Parks and Recreation (Parks & Rec) facilities.

To guide the telephone support calls, 6 structured call scripts were developed to correspond to each family session using the 5 A's model (assess, advise, agree, assist, and arrange) for behavioral change (Figure 1).[132-134] Teach-back and teach-to-goal methods were integrated into the 5 A's assess and advise components as a novel application of health literacy strategies. Each call included 4-5 TB/TTG questions per script to evaluate and promote

comprehension as well as retention of key learning objectives. For example, parents were asked to teach-back the effect of energy balance on body weight, examples of "sometimes" versus "anytime" foods, and adult and child PA recommendations. Calls also incorporated the TTG method. Any parent who answered a TB question incorrectly was given additional instruction and offered 2 additional chances to answer the question correctly (up to 2 rounds of TTG during the same call and 1 round during the next call). All calls included TB/TTG paired together and when TB was answered correctly TTG-related responses were reinforced before moving on. For simplicity we have used the term TB/TTG throughout the document. Support calls were also used to set goals with parents and collaboratively identify strategies to address barriers. These served as the 5 A's agree and assist components, respectively. Parents received the support calls 4 to 12 days following each family session. Whenever a parent missed the preceding family session, a version of the call script modified to include a brief interactive lesson was used. This lesson was also considered part of the advise component of the support calls. The modified calls offered to parents who missed the family session were termed "missed class calls" in contrast to the "follow-up calls" offered to parents who did attend the family session. Lastly, the 5 A's arrange component was fulfilled by reminding parents of the next family session or assessment appointment and confirming whether they planned to attend.

Figure 1. Integration of Support Calls with the 5 A's Model for Behavioral Change

iChoose was pilot tested using the 3-wave development process that progressively increased the role of community staff in delivery. Trained research partners (n = 2) delivered all

support calls in Wave 1, whereas call delivery responsibilities were divided between community (n = 5) and research partners (n = 2) in Wave 2 and Wave 3. In Wave 2, community staff from Danville Parks & Rec and the Pittsylvania/Danville Health District (PDHD) of the Virginia Department of Health participated in 6 group training and consultation sessions led by research staff, each of which lasted about 3 to 4 hours and was held shortly prior to delivery of program components. Approximately 45 to 60 minutes of each training session focused on support call delivery. These trainings incorporated instruction on call content and flow as well as active learning activities such as behavioral rehearsal through role playing, self-evaluation, and ongoing constructive feedback on performance. Delivery staff role played in pairs and took turns taking the support caller and the parent/caregiver roles when rehearsing upcoming calls. Community callers were given detailed feedback by experienced research callers during these behavioral rehearsals to continue improving performance. Additional behavioral rehearsal-based coaching was provided to community staff over the telephone on an as needed basis. Once program delivery had started, all support callers were also invited to reflect on their own performance and share examples of successes and challenges from calls. This activity helped to positively reinforce and disseminate effective caller strategies. Group discussion also appeared to facilitate problem solving. Training sessions for Wave 3 followed the same structure as those for Wave 2 except that behavioral rehearsal was no longer used. The number of training sessions also dropped to 4 and the proportion of the sessions focusing on support calls dropped to approximately 15 to 20 minutes per session. These modifications were made since the same staff conducted support calls for Wave 2 and Wave 3 and all callers were experienced by that point. All 3 waves of intervention delivery were completed between spring 2014 and summer 2015 while follow-up data collection continued through fall 2015.

This thesis project used data from the recruitment demographic screening, baseline parent health literacy assessment, follow-up summative evaluation, and support call process for all 3 waves. The Institutional Review Board (IRB) at Virginia Tech approved this study, and all participants gave written informed consent prior to participation. Participants were given gift cards in the amounts of $25, $25, and $50 at each of the 3 health screenings, respectively, as compensation for their time.

Target Population, Eligibility, and Recruitment

The pilot trial for the iChoose program targeted families in the health-disparate DRR. According to US Census data, a significant proportion of the residents in the DRR are black (30%), 19% of residents live below the poverty line, and only 13% have obtained a bachelor's degree or higher.[123] To be eligible to participate in the study, parent/caregiver and child dyads needed to be English-speaking and capable of physical activity (no contraindications). Children needed to be between the ages of 8 and 12 with BMI at or greater than the 85th percentile for their age and sex (overweight or obese). Families were excluded if children had major cognitive impairments or if they would have been participating in another childhood obesity treatment program at the same time as iChoose. The majority of participating families were dyads consisting of one parent and one child. However, parents were permitted to enroll with multiple children as long as each of the children met eligibility criteria. The primary strategy used for recruitment across all 3 waves involved collaboration between community partners on the POPS-CAB—namely the Children's Healthcare Center (CHC) and PDHD—and the academic research team at Virginia Tech. Pediatric physicians from the CHC and PDHD reviewed the previous 6 months of visit records to identify eligible children. Physician-signed iChoose invitation letters and program brochures were then mailed to the parents of eligible children. Trained community

and research staff called these parents approximately a week later to screen the families on demographic and health literacy characteristics as well as for willingness to participate. A secondary open referral strategy was introduced during Wave 3 recruitment. This included sending letters home through select local schools, posting flyers with regional health providers and at Parks & Rec facilities, and advertising in local newspapers. Interested families met with community staff at Parks & Rec to determine eligibility. All eligible and interested families were scheduled for enrollment appointments.

Measures and Data Collection

Data was collected at baseline, 3-month, and 6-month follow-up assessments as well as during program sessions and telephone support calls. All assessments were completed by trained research and community staff, following established protocols from the data collection manual of procedures developed for this trial.

Recruitment Demographics

Demographics of eligible families were assessed using orally administered screening questionnaires. Characteristics assessed included age, race/ethnicity, gender, annual household income, and parent education level.

Baseline Parent/Caregiver Health Literacy

Parent/caregiver health literacy was assessed using the Newest Vital Sign (NVS), a screening tool consisting of 6 orally administered questions to evaluate the individual's ability to read and apply information from a nutrition label.[135] The NVS offers several advantages compared to standard health literacy assessment tools such as the Test of Functional Health Literacy in Adults (TOFHLA).[136] The NVS can be administered more quickly than the TOFHLA, and it evaluates real-world numeracy skills that are highly relevant to iChoose

objectives (*e.g.*, teaching families to understand food labels). While there is currently no gold standard for assessing the full array of health literacy skills, the NVS has been shown to be reliable and accurate. It is able to detect limited literacy with high sensitivity (100% using a cut score of <4).[135] Consequently, an a priori cut-point of 4 was used to categorize parents in this study as having limited (<4) or adequate health literacy (≥4) based on their NVS scores.

Summative Evaluation Feedback Related to Parent/Caregiver Perceptions of Support Calls

Parent perceptions of the iChoose intervention components, including the support calls, were assessed using a summative evaluation at the end of the program. This evaluation was administered orally as part of the 3-month follow-up assessment and consisted of a combination of qualitative and quantitative questions. Qualitative questions asked parents to identify barriers that made it difficult for them to complete the calls and ways in which the delivery staff might have assisted to promote call completion. Additionally, parents were asked to identify what they liked and disliked about the calls overall. Eleven quantitative questions used 10-point Likert scales (1 = strongly disagree or completely dissatisfied, 10 = strongly agree or completely satisfied) to measure overall satisfaction with the calls and the extent to which parents agreed with a number of statements regarding the calls (*e.g.*, that the calls helped them learn the class material better, that the calls helped their families improve their eating habits, and that they felt comfortable during each call).

Support Call Process Data

Trained graduate research assistants as well as community delivery staff used structured call scripts to document detailed process data on the support calls. For each support call, they recorded call attempts, call completion status, total completed call length, and performance on TB/TTG questions. Support call scripts were designed to document adherence to the assess, advise, agree, and assist components of the 5 A's model during each support call.

Support Call Completion

Support call completion was assessed as the proportion of the 6 possible support calls completed by the parent. Partially completed calls in which at least one of the 5 A's components had been initiated was considered as completed for purposes of this measurement. The number of calls that were only partially completed was documented.

Support Call Length

Average call duration was calculated as a mean of the lengths of all fully completed support calls. Partially completed calls were omitted from this calculation since those call times did not accurately reflect the amount of time needed to complete all components of the guided call scripts.

Support Call Training and Implementation Time

The total amount of time needed to implement support calls was estimated using data on individual call lengths and the number of call attempts made according to protocol. Each call attempt was estimated to take up approximately 2 minutes. Thus total support call implementation time was estimated as the sum of all call lengths plus the number of call attempts multiplied by 2. This number was also be divided by the number of completed support calls in order to determine the average time investment for each completed support call. Additionally, the time spent in the 6 training sessions that community and research delivery staff participated in was considered as part of the implementation time.

Support Call Implementation Fidelity

Fidelity in implementing the support calls was subdivided into 2 categories: (1) fidelity to the call attempt protocol and (2) fidelity to key components of the guided call scripts. The call attempt records within each call script were scored in a binary manner based on whether or not

callers made at least 1 call attempt on each day that was required by the protocol. Call attempt fidelity was assessed for each of the 6 support calls by averaging these binary scores. Call attempt fidelity for the overall program was calculated as the mean of call attempt fidelity scores for the 6 individual support calls. Fidelity to key components of the guided scripts during call delivery was scored in a binary manner using the 5 A's framework for behavioral change. The assess component was scored based on whether or not TB/TTG questions were initiated—though not necessarily completed—for each call. The advise component applied only to missed class calls and was scored based on whether or not the missed class lesson was initiated. The agree component was scored on whether or not goal setting and/or assessment was initiated. The assist component was scored based on whether or not discussion of barriers and strategies was initiated. Call scripts contained an arrange component but were not designed to document fidelity to this component. To determine in-call fidelity for each of the 6 support calls the binary scores for each of these 4 documented components (assess, advise, agree, and assist) were averaged, then the mean of these 4 averages was calculated. In-call fidelity scores for the 6 individual support calls were averaged to determine in-call fidelity for the overall program.

Support Call Teach-back and Teach-to-Goal Performance

Performance on TB/TTG questions within support calls was evaluated using data from the call scripts which had been recorded during support calls. A recoded variable (SCORE) with a scale of 1-3 was used to evaluate TB/TTG performance. Participants who got a TB/TTG question correct on the first round received a score of 1; those who answered correctly by the second round received a score of 2; and those who did not answer correctly by the second round received a score of 3 for that TB/TTG question.

This SCORE variable for evaluating TB/TTG performance focused exclusively on the first 2 rounds of TB/TTG even though a third round of TB/TTG was given to participants who needed it. This approach was used to reduce missing data resulting from participants who did not complete a third round of TB/TTG when they needed to because they missed a specific follow-up call. Participants missed needed TB/TTG opportunities for a number of reasons including parents/caregivers missing subsequent calls (since round 3 was only offered then), only partial completion of calls, and delivery staff error. The number of times that another round of TB/TTG was needed but not completed was documented.

Some analyses of TB/TTG performance were performed separately for Wave 1 versus Waves 2 and 3 since some revisions were made to TB/TTG questions following Wave 1. However, it is important to note that the key concepts assessed by the TB/TTG questions remained the same throughout all waves of delivery.

Data Analysis

All statistical tests were completed using SPSS version 22.0 (IBM, Armonk, New York) and Microsoft Excel 2010 (Microsoft, Redmond, Washington) and included independent t-tests, one and two-way analyses of variance (ANOVA), chi-square tests, and descriptive statistics. Because of the exploratory nature of this trial the probability value to indicate significance was set at $p < 0.1$ for all quantitative comparisons.

Demographic Analysis

Descriptive statistics were used to characterize the average age, gender, marital status, education, income, and employment status of enrolled parents and caregivers as well as the average age, gender, race, and insurance coverage of enrolled and not enrolled but eligible

children. Chi-square tests were used to compare demographics of eligible children who did and did not enroll.

Aim 1: Relatedness of type of delivery staff to teach-back and teach-to-goal support call implementation fidelity, completion, and acceptability

The relationship between type of delivery staff (community or research) and implementation fidelity was evaluated using one-way ANOVAs. Analyses were conducted for both call attempt fidelity and in-call fidelity. Descriptive statistics were used to examine the completion rate, average call length, implementation time, and acceptability of using parent/caregiver support calls overall. T-tests were used to compare completion rate, average call length, and acceptability of support calls between community and research delivery.

Aim 2: Degree to which teach-back and teach-to-goal methods are necessary for adequate and limited health literacy parents/caregivers' understanding of key learning objectives

Descriptive statistics (mean ± standard deviation) were used to investigate the extent to which parents/caregivers need multiple rounds of TB/TTG to achieve parent/caregiver understanding of key learning objectives. Analyses included round 1 and round 2 of TB/TTG for each question to reduce missing data related to round 3 which occurred on a subsequent call. The need for additional instruction was determined using a 3-point scoring variable (1 = answered correctly in round 1 of TB/TTG, 2 = answered correctly in round 2 of TB/TTG, 3 = answered incorrectly in round 2 of TB/TTG). The relationship between baseline parent/caregiver health literacy level (limited or adequate) and TB/TTG performance was investigated using mixed model two-way ANOVAs. The relationship between the type of support call (missed class or follow-up) and TB/TTG performance was also evaluated using mixed model two-way ANOVAs.

The need for TB/TTG methods was also evaluated by averaging this scoring variable across all questions by wave.

Aim 3: Relatedness of baseline parent/caregiver health literacy level to support call completion and receptiveness

Descriptive statistics (mean ± standard deviation) and t-tests were used to examine the completion rate and acceptability of using parent/caregiver support calls by health literacy level.

Parent/caregiver receptiveness to support calls was evaluated using 3-month summative evaluation data. This included overall satisfaction with the calls as well as perceptions of the helpfulness of calls in learning the materials and improving healthy eating and PA behaviors reported on 10-point Likert scales (1 = strongly disagree or completely dissatisfied, 10 = strongly agree or completely satisfied). Qualitative summative feedback regarding barriers to completing calls, ways that delivery staff could improve calls, and likes and dislikes about calls were also analyzed and summarized as a measure of overall support call feasibility and acceptability. Qualitative responses documented during summative evaluation interviews were reduced to meaning units (*i.e.*, a word, phrase, or paragraph with a single meaning) and deductively grouped into themes. Only the quantitative summative data was used for analyses of call acceptability by health literacy level.

Chapter 3

RESULTS

Sample Demographics

A total of 94 parents/caregivers and 101 children participated in the 3-wave pilot trial for the iChoose program. Parent/caregiver participants were predominantly female (94%), largely employed (63%), and most had at least a high school education. The average age of parents/caregivers in the sample was 40 ± 8.8 years, and nearly half were married (49%).

The average age of children in the sample was 10 ± 1.3 years, and there were nearly equal numbers of males and females (52% and 48%, respectively). In addition, participating children were mostly black (61%) or white (36%). Most children in the sample had insurance (98%), and most had Medicaid (71%). When comparing eligible children who enrolled versus those who did not enroll across these 3 waves, there were no significant differences in demographic characteristics.

Support Call Completion and Implementation

Across 3 waves of program delivery, 350 total calls were completed including 340 fully completed and 10 partially competed calls. Excluding partially completed calls and calls for which length was indeterminable, support calls (n = 336) took an average of 25.3 ± 10.6 minutes to complete. Support calls delivered by researchers were significantly longer on average than those delivered by community partners (26.7 ± 12.1 versus 23.9 ± 8.6 minutes, $p < 0.05$). The average completion rate across all 6 biweekly calls was 62% (range of 50-74%), and completion rate did not differ significantly according to health literacy level. Including the time needed to make call attempts (estimated to be 2 minutes per attempt), an average investment of 43.1

minutes was needed for each completed support call and a total of 251.5 hours went into completing 350 support calls across 3 waves.

The call attempt protocol was delivered with 95% fidelity. Although fidelity to call attempt protocol was significantly higher for research partners (98%) than for community (92%) partners ($p < 0.05$), both groups maintained overall high fidelity to the call attempt protocol. However, community partners appeared to be more likely than research partners to complete support calls with participants (68% completion rate compared to 57%, respectively), but this trend did not reach significance ($p > 0.1$). Both research and community partners adhered to the guided call scripts with high fidelity (97% versus 98%, respectively) with no significant difference between them ($p > 0.1$). A comparison of delivery by research versus community staff can be found in Table 1 below.

Support Call Teach-back and Teach-to-Goal Performance

According to mixed model two-way ANOVAs, there was a significant main effect of health literacy level on TB/TTG performance (SCORE) for Call 1 and Call 3 during Wave 1 and for Call 1 during Waves 2 and 3 of iChoose ($p < 0.05$, 0.01, and 0.05, respectively). An interaction effect of health literacy level and question number was found for Call 3 during Wave 1 only ($p < 0.05$). For all of the calls in which TB/TTG performance was found to differ significantly according to health literacy level, parents with adequate health literacy at baseline were found to have better TB/TTG performance than those with limited health literacy.

There was also a significant main effect of support call type (missed class or follow-up) on TB/TTG performance (SCORE) for Call 5 during Wave 1 only ($p < 0.1$) such that parents completing follow-up calls were found to have better TB/TTG performance than those completing missed class calls. Additionally, an interaction effect of support call type and

question number was found for Call 3 during Wave 1 only ($p < 0.1$). Detailed TB/TTG performance results according to delivery wave, call number, call type, and health literacy level can be found in Table 2 below.

Table 1. Support Call Completion and Implementation by Delivery Staff

	Overall	Research Delivery	Community Delivery
Average Call Length (min)	25.3 (10.6)	26.7** (12.1)	23.9** (8.6)
Average Call Completion (%)	62	57	68
Average Call Attempt Fidelity (%)	95	98**	92**
Average Call Script Fidelity (%)	98	97	98

** significant at $p < 0.05$

Table 2. Teach-back and Teach-to-Goal Performance (SCORE) by Health Literacy and Call Type

WAVE 1

		Missed Class Call			Follow-Up Call			Limited HL	Adequate HL	All
		Limited HL	Adequate HL	All MC	Limited HL	Adequate HL	All FU			
Call 1**										
4 main reasons kids gain weight	**Q1**	**1.0** n = 1	**1.0** n = 1	**1.0 (0.0)** n = 2	**2.4 (0.7)** n = 9	**2.3 (0.5)** n = 6	**2.4 (0.6)** n = 15	**2.3 (0.8)** n = 10	**2.1 (0.7)** n = 7	**2.2 (0.8)** n = 17
Energy balance	**Q2**	**2.0** n = 1	**1.0** n = 1	**1.5 (0.7)** n = 2	**1.8 (0.8)** n = 9	**1.0 (0.0)** n = 6	**1.5 (0.7)** n = 15	**1.8 (0.8)** n = 10	**1.0 (0.0)** n = 7	**1.5 (0.7)** n = 17
MyPlate groups/ proportions	**Q3**	**1.0** n = 1	**1.0** n = 1	**1.0 (0.0)** n = 2	**2.2 (0.7)** n = 9	**1.3 (0.5)** n = 6	**1.9 (0.7)** n = 15	**2.1 (0.7)** n = 10	**1.3 (0.5)** n = 7	**1.8 (0.8)** n = 17
PA guidelines	**Q4**	**2.0** n = 1	**2.0** n = 1	**2.0 (0.0)** n = 2	**1.9 (0.9)** n = 9	**1.8 (1.0)** n = 6	**1.9 (0.9)** n = 15	**1.9 (0.9)** n = 10	**1.9 (0.9)** n = 7	**1.9 (0.9)** n = 17
3 signs of moderate PA	**Q5**	----------	----------	----------	**2.8 (0.4)** n = 9	**1.8 (0.8)** n = 6	**2.4 (0.7)** n = 15	**2.8 (0.4)** n = 9	**1.8 (0.8)** n = 6	**2.4 (0.7)** n = 15
Call 2										
Energy balance	**Q1**	**1.0 (0.0)** n = 5	**1.0 (0.0)** n = 2	**1.0 (0.0)** n = 7	**1.0 (0.0)** n = 4	**1.3 (0.8)** n = 7	**1.2 (0.6)** n = 11	**1.0 (0.0)** n = 9	**1.2 (0.7)** n = 9	**1.1 (0.5)** n = 18
Anytime/sometimes foods	**Q2**	**1.4 (0.9)** n = 5	**1.0 (0.0)** n = 2	**1.3 (0.8)** n = 7	**1.0 (0.0)** n = 4	**1.0 (0.0)** n = 7	**1.0 (0.0)** n = 11	**1.2 (0.7)** n = 9	**1.0 (0.0)** n = 9	**1.1 (0.5)** n = 18
Limit to sometimes foods	**Q3**	**1.2 (0.4)** n = 5	**1.0 (0.0)** n = 2	**1.1 (0.4)** n = 7	**1.3 (0.5)** n = 4	**1.3 (0.5)** n = 7	**1.3 (0.5)** n = 11	**1.2 (0.4)** n = 9	**1.2 (0.4)** n = 9	**1.2 (0.4)** n = 18

EX of replacing a sometimes with anytime food	**Q4**	**1.0 (0.0)** n = 4	**1.0 (0.0)** n = 2	**1.0 (0.0)** n = 6	**1.3 (0.5)** n = 4	**1.0 (0.0)** n = 7	**1.1 (0.3)** n = 11	**1.1 (0.4)** n = 8	**1.0 (0.0)** n = 9	**1.1 (0.2)** n = 17
Call 3*^[B]										
Should feel hungry before a meal	**Q1**	**1.0 (0.0)** n = 4	**1.0 (0.0)** n = 6	**1.0 (0.0)** n = 10	**1.4 (0.5)** n = 5	**1.0 (0.0)** n = 2	**1.3 (0.5)** n = 7	**1.2 (0.4)** n = 9	**1.0 (0.0)** n = 8	**1.1 (0.3)** n = 17
Should feel satisfied after a meal	**Q2**	**1.0 (0.0)** n = 4	**1.0 (0.0)** n = 6	**1.0 (0.0)** n = 10	**1.0 (0.0)** n = 5	**1.0 (0.0)** n = 2	**1.0 (0.0)** n = 7	**1.0 (0.0)** n = 9	**1.0 (0.0)** n = 8	**1.0 (0.0)** n = 17
Measuring portion sizes using a hand	**Q3**	**3.0 (0.0)** n = 3	**1.8 (0.4)** n = 6	**2.2 (0.7)** n = 9	**2.2 (0.8)** n = 5	**1.5 (0.7)** n = 2	**2.0 (0.8)** n = 7	**2.5 (0.8)** n = 8	**1.8 (0.5)** n = 8	**2.1 (0.7)** n = 16
Portion sizes for parents v. kids	**Q4**	**1.0 (0.0)** n = 3	**1.0 (0.0)** n = 6	**1.0 (0.0)** n = 9	**1.0 (0.0)** n = 5	**1.0 (0.0)** n = 2	**1.0 (0.0)** n = 7	**1.0 (0.0)** n = 8	**1.0 (0.0)** n = 8	**1.0 (0.0)** n = 16
Limit to screen time	**Q5**	**1.0 (0.0)** n = 3	**1.0 (0.0)** n = 6	**1.0 (0.0)** n = 9	**1.2 (0.4)** n = 5	**1.5 (0.7)** n = 2	**1.3 (0.5)** n = 7	**1.1 (0.4)** n = 8	**1.1 (0.4)** n = 8	**1.1 (0.3)** n = 16
Call 4										
4 types of info on a food label	**Q1**	**1.0 (0.0)** n = 4	**----------**	**1.0 (0.0)** n = 4	**1.0 (0.0)** n = 5	**1.0 (0.0)** n = 5	**1.0 (0.0)** n = 10	**1.0 (0.0)** n = 9	**1.0 (0.0)** n = 5	**1.0 (0.0)** n = 14
2 nutrients to limit v. to increase	**Q2**	**1.5 (0.6)** n = 4	**----------**	**1.5 (0.6)** n = 4	**1.4 (0.5)** n = 5	**1.2 (0.4)** n = 5	**1.3 (0.5)** n = 10	**1.4 (0.5)** n = 9	**1.2 (0.4)** n = 5	**1.4 (0.5)** n = 14
FoP food claims v. food labels	**Q3**	**1.0 (0.0)** n = 4	**----------**	**1.0 (0.0)** n = 4	**1.2 (0.4)** n = 5	**1.0 (0.0)** n = 5	**1.1 (0.3)** n = 10	**1.1 (0.3)** n = 9	**1.0 (0.0)** n = 5	**1.1 (0.3)** n = 14
EX of a healthy reward	**Q4**	**1.0 (0.0)** n = 4	**----------**	**1.0 (0.0)** n = 4	**1.0 (0.0)** n = 5	**1.0 (0.0)** n = 5	**1.0 (0.0)** n = 10	**1.0 (0.0)** n = 9	**1.0 (0.0)** n = 5	**1.0 (0.0)** n = 14
EX of a way to be a healthy role model	**Q5**	**1.0 (0.0)** n = 4	**----------**	**1.0 (0.0)** n = 4	**1.0 (0.0)** n = 5	**1.0 (0.0)** n = 5	**1.0 (0.0)** n = 10	**1.0 (0.0)** n = 9	**1.0 (0.0)** n = 5	**1.0 (0.0)** n = 14
Call 5[A]										
Energy balance	**Q1**	**1.0 (0.0)** n = 3	**1.0** n = 1	**1.0 (0.0)** n = 4	**1.0 (0.0)** n = 2	**1.0 (0.0)** n = 5	**1.0 (0.0)** n = 7	**1.0 (0.0)** n = 5	**1.0 (0.0)** n = 6	**1.0 (0.0)** n = 11
MyPlate groups/ proportions	**Q2**	**1.7 (1.2)** n = 3	**1.0** n = 1	**1.5 (1.0)** n = 4	**1.0 (0.0)** n = 2	**1.0 (0.0)** n = 5	**1.0 (0.0)** n = 7	**1.4 (0.9)** n = 5	**1.0 (0.0)** n = 6	**1.2 (0.6)** n = 11
Measuring portion sizes using a hand	**Q3**	**3.0 (0.0)** n = 3	**1.0** n = 1	**2.5 (1.0)** n = 4	**1.5 (0.7)** n = 2	**1.8 (0.4)** n = 5	**1.7 (0.5)** n = 7	**2.4 (0.9)** n = 5	**1.7 (0.5)** n = 6	**2.0 (0.8)** n = 11
FoP food claims v. food labels	**Q4**	**1.0 (0.0)** n = 3	**1.0** n = 1	**1.0 (0.0)** n = 4	**1.0 (0.0)** n = 2	**1.0 (0.0)** n = 5	**1.0 (0.0)** n = 7	**1.0 (0.0)** n = 5	**1.0 (0.0)** n = 6	**1.0 (0.0)** n = 11
EX of a strategy to deal with bullying	**Q5**	**1.0 (0.0)** n = 3	**1.0** n = 1	**1.0 (0.0)** n = 4	**1.0 (0.0)** n = 2	**1.0 (0.0)** n = 5	**1.0 (0.0)** n = 7	**1.0 (0.0)** n = 5	**1.0 (0.0)** n = 6	**1.0 (0.0)** n = 11

Call 6										
Lapse v. relapse	**Q1**	**1.5 (1.0)** n = 4	**1.0** n = 1	**1.4 (0.9)** n = 5	**1.0 (0.0)** n = 2	**1.0 (0.0)** n = 4	**1.0 (0.0)** n = 6	**1.3 (0.8)** n = 6	**1.0 (0.0)** n = 5	**1.2 (0.6)** n = 11
High-risk situation and a plan for it	**Q2**	**1.5 (1.0)** n = 4	**1.0** n = 1	**1.4 (0.9)** n = 5	**1.0 (0.0)** n = 2	**1.0 (0.0)** n = 4	**1.0 (0.0)** n = 6	**1.3 (0.8)** n = 6	**1.0 (0.0)** n = 5	**1.2 (0.6)** n = 11
Stressor and way to relieve stress	**Q3**	**1.0 (0.0)** n = 4	**1.0** n = 1	**1.0 (0.0)** n = 5	**1.0 (0.0)** n = 2	**1.0 (0.0)** n = 4	**1.0 (0.0)** n = 6	**1.0 (0.0)** n = 6	**1.0 (0.0)** n = 5	**1.0 (0.0)** n = 11
1 easy healthy goal after a lapse	**Q4**	**1.0 (0.0)** n = 4	**1.0** n = 1	**1.0 (0.0)** n = 5	**1.0 (0.0)** n = 2	**1.0 (0.0)** n = 4	**1.0 (0.0)** n = 6	**1.0 (0.0)** n = 6	**1.0 (0.0)** n = 5	**1.0 (0.0)** n = 11
AVERAGE:		**1.3 (0.6)**	**1.1 (0.3)**	**1.2 (0.4)**	**1.3 (0.5)**	**1.2 (0.3)**	**1.3 (0.4)**	**1.4 (0.5)**	**1.2 (0.3)**	**1.3 (0.4)**

* significant main effect of health literacy level at $p < 0.1$; ** significant main effect of health literacy level at $p < 0.05$

^ significant interaction effect of health literacy level and question number at $p < 0.05$

[A] significant main effect of call type at $p < 0.1$; [B] significant interaction effect of call type and question number at $p < 0.1$

WAVES 2 AND 3

		Missed Class Call			Follow-Up Call			Limited HL	Adequate HL	All
		Limited HL	Adequate HL	All MC	Limited HL	Adequate HL	All FU			
Call 1**										
4 main reasons kids gain weight	**Q1**	**1.0 (0.0)** n = 4	**1.8 (0.8)** n = 12	**1.6 (0.7)** n = 16	**2.3 (0.5)** n = 9	**1.5 (0.8)** n = 26	**1.7 (0.8)** n = 35	**1.9 (0.8)** n = 13	**1.6 (0.8)** n = 38	**1.7 (0.8)** n = 51
Energy balance - maintenance	**Q2a**	**1.3 (0.5)** n = 4	**1.1 (0.3)** n = 12	**1.1 (0.3)** n = 16	**1.3 (0.5)** n = 9	**1.1 (0.3)** n = 26	**1.1 (0.4)** n = 35	**1.3 (0.5)** n = 13	**1.1 (0.3)** n = 38	**1.1 (0.3)** n = 51
Energy balance - gain	**Q2b**	**1.0 (0.0)** n = 4	**1.0 (0.0)** n = 12	**1.0 (0.0)** n = 16	**1.0 (0.0)** n = 9	**1.0 (0.0)** n = 26	**1.0 (0.0)** n = 35	**1.0 (0.0)** n = 13	**1.0 (0.0)** n = 38	**1.0 (0.0)** n = 51
Energy balance - loss	**Q2c**	**1.0 (0.0)** n = 4	**1.1 (0.3)** n = 12	**1.1 (0.3)** n = 16	**1.2 (0.4)** n = 9	**1.0 (0.2)** n = 26	**1.1 (0.3)** n = 35	**1.2 (0.4)** n = 13	**1.1 (0.2)** n = 38	**1.1 (0.3)** n = 51
MyPlate groups/ proportions	**Q3**	**1.5 (1.0)** n = 4	**1.3 (0.5)** n = 12	**1.3 (0.6)** n = 16	**1.6 (0.7)** n = 9	**1.1 (0.3)** n = 26	**1.2 (0.5)** n = 35	**1.5 (0.8)** n = 13	**1.2 (0.4)** n = 38	**1.3 (0.5)** n = 51
PA guidelines	**Q4**	**1.3 (0.5)** n = 4	**1.3 (0.7)** n = 12	**1.3 (0.6)** n = 16	**1.9 (0.8)** n = 9	**1.5 (0.5)** n = 26	**1.6 (0.6)** n = 35	**1.7 (0.8)** n = 13	**1.4 (0.6)** n = 38	**1.5 (0.6)** n = 51
3 signs of moderate PA	**Q5**	**1.0 (0.0)** n = 4	**1.1 (0.3)** n = 12	**1.1 (0.3)** n = 16	**1.6 (0.5)** n = 9	**1.3 (0.5)** n = 26	**1.3 (0.5)** n = 35	**1.4 (0.5)** n = 13	**1.2 (0.4)** n = 38	**1.3 (0.4)** n = 51
Call 2										

Anytime/sometimes foods	**Q1**	**1.0 (0.0)** n = 3	**1.0 (0.0)** n = 19	**1.0 (0.0)** n = 22	**1.0 (0.0)** n = 6	**1.0 (0.0)** n = 20	**1.0 (0.0)** n = 26	**1.0 (0.0)** n = 9	**1.0 (0.0)** n = 39	**1.0 (0.0)** n = 48
Limit to sometimes foods	**Q2**	**1.7 (0.6)** n = 3	**1.2 (0.5)** n = 19	**1.2 (0.5)** n = 22	**1.0 (0.0)** n = 6	**1.1 (0.4)** n = 20	**1.1 (0.4)** n = 26	**1.2 (0.4)** n = 9	**1.1 (0.5)*** n = 39	**1.1 (0.5)** n = 48
EX of replacing a sometimes with anytime food	**Q3**	**1.0 (0.0)** n = 3	**1.0 (0.0)** n = 19	**1.0 (0.0)** n = 22	**1.0 (0.0)** n = 6	**1.0 (0.0)** n = 20	**1.0 (0.0)** n = 26	**1.0 (0.0)** n = 9	**1.0 (0.0)** n = 39	**1.0 (0.0)** n = 48
EX of a way to avoid overeating	**Q4**	**1.0 (0.0)** n = 3	**1.0 (0.0)** n = 18	**1.0 (0.0)** n = 21	**1.0 (0.0)** n = 6	**1.1 (0.2)** n = 19	**1.0 (0.2)** n = 25	**1.0 (0.0)** n = 9	**1.0 (0.2)** n = 37	**1.0 (0.1)** n = 48
Call 3										
Should feel hungry before a meal	**Q1**	**1.0 (0.0)** n = 4	**1.0 (0.0)** n = 10	**1.0 (0.0)** n = 14	**1.0 (0.0)** n = 6	**1.0 (0.0)** n = 21	**1.0 (0.0)** n = 27	**1.0 (0.0)** n = 10	**1.0 (0.0)** n = 31	**1.0 (0.0)** n = 41
Should feel satisfied after a meal	**Q2**	**1.0 (0.0)** n = 4	**1.0 (0.0)** n = 10	**1.0 (0.0)** n = 14	**1.0 (0.0)** n = 6	**1.0 (0.0)** n = 21	**1.0 (0.0)** n = 27	**1.0 (0.0)** n = 10	**1.0 (0.0)** n = 31	**1.0 (0.0)** n = 41
Measuring portion sizes using a hand	**Q3**	**1.3 (0.5)** n = 4	**1.4 (0.5)** n = 10	**1.4 (0.5)** n = 14	**1.8 (0.8)** n = 6	**1.5 (0.6)** n = 21	**1.6 (0.6)** n = 27	**1.6 (0.7)** n = 10	**1.5 (0.6)** n = 31	**1.5 (0.6)** n = 41
Portion sizes for parents v. kids	**Q4**	**1.0 (0.0)** n = 4	**1.0 (0.0)** n = 10	**1.0 (0.0)** n = 14	**1.0 (0.0)** n = 6	**1.0 (0.0)** n = 21	**1.0 (0.0)** n = 27	**1.0 (0.0)** n = 10	**1.0 (0.0)** n = 31	**1.0 (0.0)** n = 41
Limit to screen time	**Q5**	**1.0 (0.0)** n = 4	**1.0 (0.0)** n = 10	**1.0 (0.0)** n = 14	**1.0 (0.0)** n = 6	**1.1 (0.3)** n = 20	**1.1 (0.3)** n = 26	**1.0 (0.0)** n = 10	**1.1 (0.3)** n = 30	**1.1 (0.2)** n = 40
Call 4										
4 types of info on a food label	**Q1**	**1.0 (0.0)** n = 3	**1.0 (0.0)** n = 14	**1.0 (0.0)** n = 17	**1.0 (0.0)** n = 6	**1.0 (0.0)** n = 16	**1.0 (0.0)** n = 22	**1.0 (0.0)** n = 9	**1.0 (0.0)** n = 30	**1.0 (0.0)** n = 39
2 nutrients to limit v. to increase	**Q2**	**1.3 (0.6)** n = 3	**1.1 (0.3)** n = 14	**1.1 (0.3)** n = 17	**1.0 (0.0)** n = 6	**1.1 (0.3)** n = 16	**1.1 (0.3)** n = 22	**1.1 (0.3)** n = 9	**1.1 (0.3)** n = 30	**1.1 (0.3)** n = 39
FoP food claims v. food labels	**Q3**	**1.0 (0.0)** n = 3	**1.0 (0.0)** n = 14	**1.0 (0.0)** n = 17	**1.0 (0.0)** n = 6	**1.0 (0.0)** n = 16	**1.0 (0.0)** n = 22	**1.0 (0.0)** n = 9	**1.0 (0.0)** n = 30	**1.0 (0.0)** n = 39
EX of a healthy reward	**Q4**	**1.0 (0.0)** n = 3	**1.0 (0.0)** n = 14	**1.0 (0.0)** n = 17	**1.0 (0.0)** n = 6	**1.0 (0.0)** n = 16	**1.0 (0.0)** n = 22	**1.0 (0.0)** n = 9	**1.0 (0.0)** n = 30	**1.0 (0.0)** n = 39
EX of a way to be a healthy role model	**Q5**	**1.0 (0.0)** n = 3	**1.0 (0.0)** n = 14	**1.0 (0.0)** n = 17	**1.0 (0.0)** n = 6	**1.0 (0.0)** n = 16	**1.0 (0.0)** n = 22	**1.0 (0.0)** n = 9	**1.0 (0.0)** n = 30	**1.0 (0.0)** n = 39
Call 5										
Energy balance	**Q1**	**1.2 (0.4)** n = 5	**1.0 (0.0)** n = 11	**1.1 (0.3)** n = 16	**1.0 (0.0)** n = 4	**1.0 (0.0)** n = 13	**1.0 (0.0)** n = 17	**1.1 (0.3)** n = 9	**1.0 (0.0)** n = 24	**1.0 (0.2)** n = 33
MyPlate groups/ proportions	**Q2**	**1.0 (0.0)** n = 5	**1.1 (0.3)** n = 11	**1.1 (0.3)** n = 16	**1.0 (0.0)** n = 4	**1.0 (0.0)** n = 13	**1.0 (0.0)** n = 17	**1.0 (0.0)** n = 9	**1.0 (0.2)** n = 24	**1.0 (0.2)** n = 33

Measuring portion sizes using a hand	**Q3**	**1.4 (0.9)** n = 5	**1.5 (0.5)** n = 11	**1.4 (0.6)** n = 16	**1.0 (0.0)** n = 4	**1.4 (0.5)** n = 13	**1.3 (0.5)** n = 17	**1.2 (0.7)** n = 9	**1.4 (0.5)** n = 24	**1.4 (0.5)** n = 33
EX of a strategy to deal with bullying	**Q4**	**1.0 (0.0)** n = 5	**1.0 (0.0)** n = 11	**1.0 (0.0)** n = 16	**1.0 (0.0)** n = 4	**1.0 (0.0)** n = 13	**1.0 (0.0)** n = 17	**1.0 (0.0)** n = 9	**1.0 (0.0)** n = 24	**1.0 (0.0)** n = 33
Call 6										
Lapse v. relapse	**Q1**	**1.0 (0.0)** n = 4	**1.3 (0.5)** n = 7	**1.2 (0.4)** n = 11	**1.3 (0.5)** n = 4	**1.2 (0.5)** n = 22	**1.2 (0.5)** n = 26	**1.1 (0.4)** n = 8	**1.2 (0.5)** n = 29	**1.2 (0.5)** n = 37
High-risk situation and a plan for it	**Q2**	**1.0 (0.0)** n = 4	**1.0 (0.0)** n = 6	**1.0 (0.0)** n = 10	**1.0 (0.0)** n = 4	**1.1 (0.3)** n = 22	**1.1 (0.3)** n = 26	**1.0 (0.0)** n = 8	**1.1 (0.3)** n = 28	**1.1 (0.2)** n = 36
Stressor and way to relieve stress	**Q3**	**1.0 (0.0)** n = 4	**1.0 (0.0)** n = 6	**1.0 (0.0)** n = 10	**1.0 (0.0)** n = 4	**1.0 (0.2)** n = 22	**1.0 (0.2)** n = 26	**1.0 (0.0)** n = 8	**1.0 (0.2)** n = 28	**1.0 (0.2)** n = 36
1 easy healthy goal after a lapse	**Q4**	**1.0 (0.0)** n = 4	**1.0 (0.0)** n = 6	**1.0 (0.0)** n = 10	**1.0 (0.0)** n = 4	**1.0 (0.0)** n = 21	**1.0 (0.0)** n = 25	**1.0 (0.0)** n = 8	**1.0 (0.0)** n = 27	**1.0 (0.0)** n = 35
AVERAGE:		**1.1 (0.2)**	**1.1 (0.2)**	**1.1 (0.2)**	**1.2 (0.3)**	**1.1 (0.2)**	**1.1 (0.2)**	**1.1 (0.2)**	**1.1 (0.2)**	**1.1 (0.2)**

** significant main effect of health literacy level at $p < 0.05$

Summative Evaluation Feedback

Out of the 94 families that participated in the iChoose program, 61 (60%) completed the post-intervention summative including 52 parents who provided feedback regarding follow-up support calls and 41 who provided feedback regarding missed class calls. Results indicated high levels of satisfaction and acceptability toward support calls and did not differ meaningfully based on research or community partner delivery of calls. Only one rating differed significantly according to health literacy level. According to a one-way ANOVA, parents with limited health literacy at baseline expressed stronger agreement that follow-up support calls helped improve family eating habits compared to those with adequate health literacy (9.3 (1.9) versus 7.7 (2.7), p = 0.056). Those with limited health literacy also agreed more strongly that follow-up calls helped improve family PA habits (8.5 (2.8) versus 7.1 (2.6)), but this trend did not reach significance. Detailed quantitative feedback results for support calls according to health literacy level can be found in Table 3 below.

Table 3. Parent Support Call Quantitative Feedback by Health Literacy

	Overall	**Limited HL**	**Adequate HL**
The iChoose telephone calls helped me learn the class material better	8.1 (2.7)	8.3 (3.1)	8.1 (2.5)
Some of the questions from the call were hard	3.8 (3.3)	3.2 (3.0)	4.0 (3.4)
In the future, I think you should keep using the calls as part of the iChoose program	8.6 (2.4)	9.1 (2.1)	8.5 (2.5)
I was satisfied with the length of the calls	8.6 (2.4)	9.0 (2.3)	8.4 (2.4)
The calls helped my family improve our eating habits	8.1 (2.6)	9.3 (1.9)*	7.7 (2.7)*
The calls helped my family be more active	7.5 (2.7)	8.5 (2.8)	7.1 (2.6)
I felt comfortable during each call	9.5 (1.2)	9.7 (0.9)	9.5 (1.3)
Overall, how satisfied were you with the calls?	9.1 (2.0)	9.4 (1.9)	8.9 (2.1)
Overall, I was satisfied with the calls I got after the time(s) I missed class	9.3 (1.7)	9.2 (2.5)	9.3 (1.2)
I was satisfied with the length of the calls for the missed class	8.7 (2.2)	8.5 (2.8)	8.8 (2.0)
In the future, I think you should keep using the missed class calls as part of the iChoose program	9.1 (1.8)	9.0 (2.5)	9.2 (1.4)

Questions used 10-point Likert scales (1 = strongly disagree or completely dissatisfied, 10 = strongly agree or completely satisfied)
* significant at $p < 0.1$

Four free-response questions were also administered to identify what parents liked and disliked about support calls, what challenges hindered completion of calls, and what the iChoose team could have done differently to promote completion of calls. When asked about their likes and dislikes regarding support calls, parents provided a total of 81 (75%) positive responses and 27 (25%) negative responses. A summary of the results consisting of the 3 most common responses including an example quote for each can be found in Table 4 below. Qualitative analysis showed many parents appreciated having support calls as an opportunity to reinforce and clarify class material, to hold them accountable to healthy goals, and to interact with program staff. Findings also revealed that some parents found the calls to be too long and repetitive as well as challenging to schedule around other commitments. Some even suggested using alternative forms of communication, such as emails and texts, in place of calls. Results from this mixed methods evaluation help to highlight the strengths of the iChoose program as well as to reveal areas that may be improved upon for increased call completion and acceptability.

Table 4. Parent Support Call Qualitative Feedback

Interview Question	3 Most Common Themes	Sample Quotes
What did you like about the telephone calls?	Review/clarification of material	"Chance to go over things [I] didn't understand, liked that [calls] reiterated information to make things clear"
	Interaction with staff	"Staff [was] sweet and polite (knowledgeable about content and able to answer questions, provided positive reinforcement)"
	Accountability/reminder of commitments	"Really good reminder, put you back on track if you slacked off"

What did you dislike about the telephone calls?	Length	"Length too long, repetitive"
	Scheduling	"Scheduling calls: [being a] single mom with 3 kids made it difficult"
	Content	"It was redundant, too much rehashing for me. I like to read things on my own"
What made it hard for you to complete these calls?	Scheduling conflicts	" Life: work and other commitments"
	Format	"Didn't want to do it. Too long and inconvenient"
	Technical difficulties	"Didn't have phone 'hooked up' all the time."
What could our iChoose team have done differently to help you complete more calls?	Alternate method of contact	"Calls were ok: good refreshers; emails might make it easier to accommodate schedule -- communication with texts is better"
	Call format change	"Shorter and less repetitive"
	Call schedule change	"Call earlier instead of later"

Chapter 4

DISCUSSION

Although childhood obesity is a widely recognized public health concern and low health literacy in parents has been linked to increased obesity risk in children, there has been little to no research into the implementation of health literacy-sensitive TB/TTG strategies to address healthy eating, physical activity, and weight loss in the context of childhood obesity intervention program. The purpose of our paper was to explore the use of these strategies within a community-based participatory research (CBPR) approach to improve health disparities in diverse, low literate rural populations. This study provided novel information regarding the feasibility and acceptability of using support calls incorporating TB/TTG methods within a childhood obesity intervention including detailed evaluations based on type of delivery staff and parent health literacy level.

Both Community and Research Delivery Staff Delivered Support Calls with High Levels of Implementation Fidelity and Acceptability and Comparable Completion Rates

Consistent with our hypothesis, community staff delivered support calls with high levels of fidelity and acceptability comparable to research staff when community staff was provided with thorough training and ongoing support and supervision. These results suggest that even a small number of training and consultation sessions led by trained research staff and incorporating active learning techniques can help empower community staff to deliver behavioral interventions with high quality.

Additionally, the fact that community partners achieved higher completion rates than research partners for support calls – though this trend did not reach significance – seems to suggest that other factors unique to community staff may offer advantages for intervention

delivery. For example, it's possible that parents felt more comfortable discussing health-related behavior changes with callers known to be nurses. Another possibility is that they simply felt more at ease speaking to fellow members of the local community.

Although community-delivered support calls were found to be significantly shorter on average than researcher-delivered calls, adherence to call scripts did not differ significantly by type of delivery staff. Thus it may be that community staff simply covered the same learning objectives more efficiently than research staff.

Parents with Adequate Health Literacy at Baseline were Found to Have Better TB/TTG Performance on Certain Support Calls Than Those with Limited Health Literacy

Consistent with our expectation, parents on average required more than 1 round of TB/TTG to demonstrate understanding of key learning objectives from the intervention across all 3 waves of delivery. However, especially in the latter 2 waves of delivery, the overall average number of rounds required was very close to 1. This may suggest that for certain parents and questions only a single round of TB/TTG may be sufficient to help reinforce those learning objectives. Results did show a significant effect of health literacy level on TB/TTG performance for select calls. As hypothesized, parents with limited health literacy required additional TB/TTG opportunities to a significantly greater extent than those with adequate health literacy for those calls alone. Our study design does not provide enough information about the causal pathway leading to differential TB/TTG performance to draw firm conclusions regarding the impact of health literacy level on the need for additional rounds of TB/TTG. However, these results suggest that limited health literacy level may play a role in difficulty understanding certain concepts in our intervention. Collection and analysis of this type of data can serve an important role in future improvement and tailoring of intervention strategy so that valuable instructional

resources can be used to target the most challenging concepts and individuals who may need the most support to understand them.

We also hypothesized that parents would demonstrate better performance on TB/TTG questions for missed class calls than for follow-up calls due to a difference in the amount of time allowed to pass between instruction and assessment. However, the results did not support this hypothesis. For the most part, TB/TTG performance did not differ significantly by call type. Even when a significant difference was found, it occurred in a direction opposite of expectations or – in the case of the interaction effect of support call type and question number – the direction of the effect differed by question within the same call. Although parents completing follow-up calls experienced a longer delay period between instruction and assessment, it is possible that the longer and more interactive instruction they received in class helped to improve retention of that information. Additionally, it seems possible that parents who attended classes and thus completed follow-up calls were more motivated and engaged with the intervention content in the first place.

As mentioned above, TB/TTG performance improved following Wave 1 of delivery such that the average number of TB/TTG rounds required for Waves 2 and 3 combined became very close to 1 (*i.e.*, most parents answered TB/TTG questions correctly on their first attempt). It is important to note that changes were made to the TB/TTG questions as well as other components of the iChoose program following completion of Wave 1 delivery. In an effort to continue improving the program, we made careful modifications guided by self-evaluation as well as Wave 1 participant feedback.

During this process, the data we collected on TB/TTG performance during Wave 1 was especially valuable to the delivery team as it helped to highlight the concepts that participants

appeared to struggle with the most. When making subsequent changes to our programming, we focused most on these concepts making sure to communicate them clearly and consistently in our written materials as well as in-person instruction and TB/TTG assessments. Since TB/TTG performance improved after these program updates, it is possible that our purposeful changes aiming to enhance comprehension of both initial instruction and TB/TTG questions contributed to this improvement. Additional testing is needed to elucidate these effects and further explore the potential of TB/TTG strategies to not only to clarify concepts following instruction but also to improve the quality of the original educational session.

Lastly, it is worth noting that TB/TTG performance data can help to highlight not only the most challenging programming topics but also the most easily grasped ones. For example, we found in our study that certain TB/TTG questions were answered correctly on the first attempt by every parent that completed the call regardless of health literacy level or call type (10 questions in Wave 1 and 12 questions in Waves 2 and 3). Concepts addressed by these questions included healthy ways for families to reward themselves, ways for parents to be healthy role models, and strategies for children to deal with bullying.

As community-research partnerships continue to seek more resource-efficient and effective strategies for addressing the most pressing community health issues, data such as that which we collected on TB/TTG performance will help to identify a smaller subset of questions and concepts for which individualized live call support and feedback may be most important. For the remaining concepts, which all participants were able to demonstrate mastery of even without further instruction, we feel it is highly advisable to explore less time and cost-intensive ways to reinforce these messages including but not limited to Interactive Voice Response (IVR) calls.

Support Call Completion and Receptiveness Largely Did Not Differ by Health Literacy Level

Since we expected that parents with limited health literacy at baseline would require additional rounds of TB/TTG more than those with adequate health literacy, there was concern that parents with limited health literacy might be put off by the multiple rounds of TB/TTG. Thus, we hypothesized that parents with limited health literacy might have lower call completion rates and/or less positive views toward the support calls compared to parents with adequate health literacy. In contrast to our expectations, neither call completion nor receptiveness was significantly lower among parents with lower health literacy levels. Not only did support call receptiveness remain high across health literacy levels, parents with limited health literacy at baseline actually expressed stronger agreement that follow-up support calls helped improve family eating habits compared to those with adequate health literacy.

These findings may be partially explained by the fact that health literacy level had a fairly limited correlation with the need for TB/TTG among participants. Summative feedback also revealed that many parents appreciated that support calls gave them the opportunity to review and clarify intervention content, interact with program staff, and be held responsible for their commitments. These findings are consistent with limited evidence in the literature indicating that participants enjoy the individualized support, instruction, and follow-up provided by telephone calls incorporating TB. [99] While a small number of parents in the iChoose program did express that the TB/TTG process was intimidating, more seemed to appreciate the various forms of support offered by the calls. It is possible that the conversational non-text format used for these calls also helped parents feel comfortable during TB/TTG assessments.

Our findings that parents with limited health literacy were just as likely to complete support calls incorporating TB/TTG strategies and to view them positively is especially encouraging in light of limited evidence suggesting patients with lower literacy may benefit ven more from health interventions incorporating TB/TTG calls than patients higher literacy. [93,96] Further testing is needed to clarify the benefits of these support calls including whether they might be particularly helpful to parents with lower health literacy.

Limitations

While the iChoose program was developed using evidence-based principles, as a CBPR-tailored intervention it was very much designed to meet the specific needs of the rural health-disparate Dan River Region (DRR).[131] As such, these findings may have limited generalizability to other communities, especially those that are more urban and/or that differ significantly from the DRR demographically. On the other hand, since the DRR is a federally designated medically under-served area known to suffer from educational, economic, and health disparities, similar regions for which these findings may be more generalizable are also likely to be some of the most in need of effective health promotion strategies.

Another notable limitation lies in the small size and nature of this pilot trial intervention. Due to financial realities as well as the regional population size and structure, the statistical power of our data is limited. However, this CBPR approach which engaged community partners during all phases of research from program selection and adaptation to eventually delivery offers other advantages of developing and strengthening community capacity and sustainability of interventions.

Conclusion

In summary, our study demonstrated that it is feasible to implement health literacy-sensitive TB/TTG strategies with high fidelity as part of a rural community-based childhood obesity intervention such that they are highly acceptable to participants. Using a 3-wave development process that progressively shifted program delivery responsibilities, we were also able to show that properly trained community partners could deliver the same support call content with similarly high fidelity, completion, and acceptability. Although parental baseline health literacy level (adequate or limited) was not as strongly correlated with additional need for TB/TTG opportunities and on program perception as we anticipated, our findings open up different possibilities to utilize these strategies while using precious resources more efficiently. Future research should explore the feasibility and acceptability of more time and cost-efficient means of deploying these strategies (*e.g.*, IVR versus live calls) as well as moving beyond feasibility and acceptability in order to connect these strategies to primary outcomes of interest (*e.g.*, child weight, body mass index z-score (BMIz), and/or prevalence of overweight and obesity).

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