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Recruitment planning for clinical trials with a vulnerable perinatal adolescent population using the Clinical Trials Transformative Initiative framework and principles of partner and community engagement

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ABSTRACT

Recruitment planning is needed to establish a foundation for obesity prevention research with high risk, disadvantaged perinatal adolescent populations. In the context of developing clinical trial protocols, investigators partnered with Mississippi's Nutrition Program for Women, Infants and Children (WIC) and adopted the Clinical Trials Transformative Initiative (CTTI) framework for recruitment planning to identify and mitigate challenges to recruitment early in the clinical trial development process. The recruitment protocol consisted of 20 passive strategies grounded in principles of partner and community engagement and was flexible, accommodating, altruistic, community-focused, and minimally burdensome to partners and participants. The recruitment goal included 150 adolescent-coparticipant dyads and 145 dyads (96.7%) were successfully recruited. Investigators demonstrated the feasibility of recruiting a disadvantaged and vulnerable perinatal adolescent population that is underrepresented in health research, in one of the most persistently impoverished and poor health regions in the U.S. Four important aspects of recruitment planning using the CTTI framework are discussed including: (1) establishing partnerships with trusted community resources is a paramount investment; (2) dedicating time and resources to know and go to your community is invaluable; (3) fostering trust by offering convenient, continuous and clear communication; and (4) encouraging collaboration and participation through limiting partner and participant burden. Establishing organizational and community partnership requires a substantial amount of invaluable time and fosters recruitment success. Following the CTTI recommendations for recruitment planning led to a robust recruitment protocol that will be used in future intervention trials with an understudied perinatal adolescent population with high risk for poor maternal and fetal health outcomes.

1. Introduction

Recruitment is the process of locating and informing potential participants about a research study [1]. The representativeness and size of a study sample are critical goals of recruitment [1–3] and coupled with rigorous methodology, are integral to ensuring proper

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interpretation of data [4,5]. Studies of populations disproportionately burdened by poor health are commonly confronted with challenges to recruitment resulting in the underrepresentation of health disparity populations in research [5,6]. The National Institute on Minority Health and Health Disparities defines *health disparity* as a difference in health outcomes adversely affecting disadvantaged populations including socioeconomically underprivileged, racial and ethnic minority groups, and rural residents [7–9]. The scientific discovery of factors contributing to disparities is hindered by the underrepresentation of health disparity populations in research, leaving investigators with unanswered questions and lacking solutions [10].

In 1993, the National Institutes of Health Revitalization Act [11] directed all Institutes to establish guidelines for inclusion of women and minority groups in research. Nearly three decades later, racial and ethnic minority populations remain inadequately represented [12–14] and have persistently higher rates of chronic disease and premature death compared to Whites [15]. Reported barriers to research participation include limited financial resources [16–18], lack of transportation and child care [17,18], low literacy [18], mistrust [16,17], and among researchers, difficulties establishing community partnerships and connecting with participants [5]. Mitigating barriers to increase research participation among health disparity populations is a national priority [19–21].

Black, pregnant adolescents in socioeconomically disadvantaged communities represent a particularly vulnerable and understudied perinatal population with high risk for poor health and disease [22,23]. Adolescent pregnancy (<20 years [24]) is disproportionately prevalent among Black youth compared with White youth (27.6 and 13.4 per 1000, respectively) and is a prominent risk factor for obesity [25–29]. Normal pubertal growth is associated with increased weight in adolescence [30] and Black female and rural adolescents are at highest risk for excessive adiposity [27–29,31]. Pregnancy exacerbates preexisting risks [26,32] and predicates a trajectory of maternal and child obesity [25,33–36]. Without targeted recruitment, perinatal adolescents with high risk for obesity may remain underrepresented in health research.

One of the challenges to advancing perinatal health research with adolescents is a constellation of additional barriers to research participation including stigma associated with adolescent pregnancy, physiological changes amid puberty [37], psychosocial immaturity, parental consent, and family dynamics [38–40]. Mitigation strategies have included partnerships with local clinical and public health providers, family engagement, and in-person recruitment [41–45]. However, there remains a critical need for feasibility studies and the dissemination of effective recruitment strategies for populations underrepresented in health research [1,16,46–50].

The *Teen Mom Study* was designed as formative research to inform the development of obesity prevention interventions tailored for a socioeconomically disadvantaged, predominantly Black perinatal adolescent population in a rural region of Mississippi [51]. Identifying successful recruitment strategies is integral to clinical trial design and thus, was a secondary aim of the *Teen Mom Study*. The recruitment goal included 150 adolescent-parent/guardian dyads. Investigators anticipated recruitment would be challenging and took a structured, community-engaged approach to planning. This paper describes the recruitment planning process, outlines the recruitment protocol, provides descriptive characteristics of the resultant study sample, and discusses important lessons learned and implications for clinical trial development.

2. Methods

2.1. Community partner, setting and target population

Public health services are ideal settings for the prevention and treatment of obesity among high-risk, socioeconomically disadvantaged populations accessing government assistance programs [35]. In particular, the Special Supplemental Nutrition Program for Women, Infants and Children (WIC) is a federally-funded, state-run public health service providing supplemental foods and nutrition counseling to low-income women, infants, and children at nutritional risk [52]. In Mississippi, WIC is a program of the State Department of Health, implemented locally through county health departments and at the time of this study, WIC clients were required to enroll and receive benefits (nutrition counseling and food packages) in-person [53]. WIC is uniquely positioned as a life course approach to promote health and prevent disease during critical biological periods of growth and development among a vulnerable population. Thus, engaging WIC, ensuring a shared interest in obesity prevention, and forging an academic-community partnership were critical first steps in recruitment planning.

The target population included socioeconomically disadvantaged perinatal adolescents (<20 years) in the Mississippi Delta. The Delta is a culturally and geographically distinct 18-county rural region of Mississippi that is plagued by decades of persistent poverty, high teen birth rates, and poor health [54]. In comparison with the United States (U.S.) and Mississippi, residents of the Delta Region and in particular, Blacks compared with Whites have higher prevalence of poor health risk factors and health outcomes, and bear a disproportionate burden of social inequalities [55,56]. Despite overall national declines in adolescent pregnancy in recent decades, teen birth rates in the Mississippi Delta are the highest in the U.S. and have not declined since 2006 [57]. On average, teen birth rates are 154% higher among Delta residents (55.3 per 1000) compared with the State (36 per 1000), and among Black youth (40 per 1000) compared with White youth (26 per 1000) statewide [57]. Table 1 describes obesity risk factors and health indicators for residents of 13 of the 18 Delta Counties (included in this study) compared with the U.S. and Mississippi.

2.2. Recruitment planning framework

The Clinical Trials Transformative Initiative (CTTI) framework for effective clinical trial recruitment planning was used to guide the development of a recruitment protocol for the target population [58]. The CTTI framework is comprised of recommendations for trial design and protocol development, trial feasibility and site selection, and recruitment communication. When applied, these recommendations are thought to afford investigators and stakeholders the opportunity to identify and mitigate challenges to recruitment during early stages of clinical trial development.

Investigators also approached the planning process and conceptualized discrete recruitment strategies according to the Patient-Centered Outcomes Research (PCOR) principles of engagement [59] and the Clinical and Translational Science Awards (CTSA) Consortium community engagement principles [60]. The six partner and patient PCOR principles include trust, honesty, co-learning, transparency, reciprocity, and partnership and respect. The nine CTSA principles are organized across three interdependent categories including considerations prior to community engagement (have a clear purpose and be knowledgeable about the community); necessities for engagement to occur (go to the community and accept community self-determination); and elements of engagement success (partnership, respect for diversity, assets, flexibility, and commitment). The principal investigator (PI) led the recruitment planning process and ensured the principles of partner and community engagement were considered in planning and implementing the recruitment protocol. Oversight was provided by mentor investigators (BMB, SJH, JBM, and MAW) and input from WIC providers and clients were solicited and integrated throughout the planning and implementation processes.

3. Recruitment protocol

Following the CTTI recommendations and applying the principles of partner and community engagement resulted in a multicomponent

Table 1
Health indicators and obesity risk factors among select Delta Counties compared with Mississippi and the United States.

	Sociodemographic						Environment				Health Indicators and Obesity Risk Factors									
	B, %	Children in poverty, %			Median household income, $		Rural, %	Severe housing issues	LHF access	LPA access	Teen births, per 1000			Low birth weight, %			FI, %	PIA, %	CHR	
		All	B	W	All	B	W					All	B	W	All	B	W			
United States	13.4	18	32	11	60,293	41,511	67,937	23	18	7	84	19	12	4	8	11	5	12	23	–
Mississippi	37.4	28	43	14	44,700	41,361	70,632	50.7	16	11	54	36	40	26	12	16	8	19	32	–
Delta County																				
Bolivar	63.6	39	55	28	33,100	21,500	53,400	54	20	24	39	43	55	20	13	15	9	28	33	63
Coahoma	76.6	50	72	20	29,400	23,100	57,100	32	16	16	72	63	69	28	17	19	6	30	36	80
Holmes	82.0	46	60	15	26,400	19,00	51,000	86.8	18	33	27	39	–	–	14	15	8	34	28	77
Humphreys	74.8	56	64	5	28,500	23,200	56,100	49.8	23	13	36	50	–	–	14	–	–	31	28	66
Issaquena	63.0	51	85	58	29,600	18,200	60,500	100	20	27	18	–	–	–	24	–	–	32	43	73
Leflore	74.0	49	65	10	29,200	17,100	58,000	17.7	21	31	69	51	53	37	14	16	9	30	33	75
Panola	49.5	34	33	20	39,200	30,400	49,300	78.9	14	12	18	55	60	48	12	15	8	21	40	47
Quitman	70.9	55	56	66	27,800	21,600	38,100	57	16	24	17	54	53	64	18	18	11	29	41	78
Sharkey	70.3	49	32	6	28,900	24,300	54,900	100	11	16	2	72	–	–	16	–	–	27	29	82
Sunflower	73.2	42	51	2	31,300	25,200	53,400	45.8	22	25	28	46	55	14	15	16	11	29	33	72
Tallahatchie	56.1	41	58	11	32,700	19,800	43,100	80.9	12	30	27	59	65	42	16	18	11	19	30	57
Tunica	77.0	44	31	6	33,100	33,300	46,600	66	25	10	57	76	81	43	13	14	7	28	31	70
Washington	71.9	52	55	27	34,000	24,000	52,900	17.5	19	19	77	58	64	36	14	15	8	28	36	71

Source: University of Wisconsin Population Health Institute. County Health Rankings Report 2020.
Abbreviations: B, Black or African American; W, White or Caucasian; %, percent; LHF, limited access to healthy foods; LPA, limited access to physical activity resources; FI, food insecurity; PIA, physical inactivity; CHR, County Health Ranking.
Note: Blank values reflect unreliable or missing data; Mississippi County Health Rankings are rank out of total 82 Mississippi Counties

recruitment protocol consisting of 20 discrete passive strategies. Passive recruitment approaches create awareness of the study among the target population and allow prospective participants to approach researchers [61]. Table 2 presents the CTTI recommendations [58] and application in the current study. Table 3 defines the 20 discrete passive strategies, specifies the actors involved in identifying and/or implementing each strategy and identifies the PCOR [59] and/or CTSA [60] principles related to each strategy. The applications of the CTTI recommendations and the principles of partner and community engagement and resultant recruitment protocol are described in detail below. The Institutional Review Boards of the University of Mississippi Medical Center (#2017–0024) and the Mississippi State Department of Health (#090717) approved all participant recruitment procedures.

3.1. Identify and engage all stakeholders and partners

The CTTI recommendations highlight the importance of identifying and engaging stakeholders as equal partners in trial design, protocol development and communication planning; identifying where participants seek treatment and relevant information; and to enhance trial feasibility, ensuring appropriate site selection for recruitment. Together, these three recommendations were a cornerstone in planning for participant recruitment, which was anchored by the academic-community partnership between the investigative team and WIC.

In 2014, the PI emailed the WIC director requesting a meeting to discuss the potential for research collaboration. Throughout a series of in-person meetings over 12 months, the sharing of knowledge, experiences and backgrounds brought to bear trust and mutual respect, serving as the foundation upon which a partnership began. On one occasion, the PI traveled with the WIC director to a county health department and WIC food distribution center to observe the implementation of WIC including in-person procedures for client enrollment, nutrition counseling, and the distribution of WIC food packages. This was a pivotal experience for the PI, realizing the importance of being accessible, available and amenable to diverse needs and wants and embracing unique assets of the WIC community. These were important insights gleaned early in the planning process, which impacted later decisions pertaining to WIC's role in conducting participant recruitment and adolescent participant compensation.

In 2015, the Mississippi State Department of Health unexpectedly appointed an interim WIC director who was in support of maintaining an academic-community partnership. Through this abrupt leadership transition, the PI gained a critical appreciation not only for the importance of organizational partnerships centered around a shared goal; but also, for cultivating genuine relationships with people. In 2016, a permanent WIC director was appointed. During this leadership transition, the PI met with both the outgoing and incoming directors in an effort to retain the momentum of a growing partnership. Fortuitously, the PI and incoming WIC director had an existing professional relationship, having been former close colleagues with the Mississippi State Department of Health. The academic-community partnership strengthened under the leadership of this WIC director, whom as of this publication, planned to retire in late 2021. In essence, when building partnerships, success comes when the 'building' never ceases.

3.2. Ensure appropriate site selection

Beginning in 2016, the PI worked closely with the WIC director and regional supervisors to better understand the organizational context of WIC. Over the course of one year, the PI made frequent contact with county-level WIC providers through in-person visits, phone calls, emails and using qualitative interviewing to understand their opinions, experiences and perspectives of the clients they served [62]. Through these encounters and experiences, the PI developed a deep appreciation for WIC as a trusted and relied upon community resource among families in the Delta Region; critical insight for identifying where the target

Table 2
Framework for strategic recruitment planning for the *Teen Mom Study*.

CTTI Recommendation	Strategic Application
Trial Design and Protocol Development	
Identify and engage all stakeholders as equal partners in the process	• Engaged and partnered with WIC three years prior to recruitment. • Engaged community advisory board as stakeholder (MCCTR). • Adopted principles of partner and community engagement.
Ensure the relevance of the scientific question to stakeholders	• Confirmed by WIC during partnership engagement in 2014. • Community advisory board was component of funding entity.
Reduce complexity and participant burden	• Minimized burden for WIC to conduct participant engagement. • Mitigated participant transportation barriers. • Research participation length: approximately 60 min. • Utilized mobile phone convenient and frequent communication.
Develop realistic eligibility criteria	• Assessed Delta Region and WIC sociodemographic characteristics. • Adapted criteria according to population while retaining study integrity including adjustments to coparticipant criterion, adding counties to recruitment catchment area and adopting word-of-mouth strategy.
Have realistic communication budget	• Printing of recruitment flyers ($216). • Monthly state-issued mobile phone fee ($50 per month; $600 annual).
Optimize data collection to answer scientific questions	• Sought WIC director insight on survey questions and it was recommended that the surveys be interviewer-administered. • Survey questions limited to research question (*outcomes not reported*).
Trial Feasibility and Site Selection	
Conduct evidence-based trial feasibility analysis	• Spent time with WIC and traveling to county health departments to understand organizational processes and procedure and to identify opportunities for and potential barriers to recruitment.
Establish realistic metrics and milestones	• Recruitment metrics and milestones were not formally identified.
Develop an adequate budget and resources for recruitment	• Diapers and wipes adolescent compensation ($2414). • Monetary gift card coparticipant compensation ($9000). • Distance traveled (about 19,300 miles) and cost for travel (about $10,904). • Investigator time (50% FTE and fringe; about $52,000 per annum).
Ensure appropriate site selection	• WIC is ideal partner and recruitment site (county health departments).
Engage site performance monitoring	• WIC was engaged in the recruitment planning process, which enabled identification and mitigation of barriers (provider time and resources).
Recruitment Communication Planning	
Identify all stakeholders and partners (critical to study communication)	• Local WIC providers; stakeholder and partner. • Community advisory board, MCCTR; stakeholder. • Adolescents and their families (primarily biological mother); partners.
Identify participant locations based on where they seek treatment and relevant information	• WIC identified as a community trusted and frequented resource. • CAB identified school clinic and mentors as trusted sources. • Family and community emerged as trusted sources of information.
Develop and test tailored messages	• Study flyer included mention of diapers and wipes. • WIC providers promoted convenient participation and compensation.
Develop creative material and select appropriate delivery channels	• Recruitment flyer designed to be appealing to Black WIC clients. • Engagement conducted by WIC providers disseminating flyers in-person. • Word-of-mouth by participants led to significant snowball recruitment.
Have realistic communication budget	• Recruitment flyer printing ($216). • Monthly state-issued mobile phone fee ($50 per month; $750 total). • Participant word-of-mouth ($0). • Infographic to communicate results to WIC community ($250).
Monitor and evaluate the recruitment process and performance with meaningful metrics	• Conducted recruitment study; monitored strategies and recruitment. • Established recruitment goal (150 adolescent-coparticipant dyads). • Tracked counties and recruitment sources represented by participants.

Abbreviations: CTTI, Clinical Trials Transformative Initiative; WIC, Special Supplemental Nutrition Program for Women, Infants and Children; MCCTR, Mississippi Center for Clinical and Translational Research; FTE, full-time equivalent.

population frequents and seeks relevant information.

The PI also sought insight from a community advisory board to help identify appropriate outreach and engagement sites in the Delta Region. The community advisory board was developed by the Mississippi Center for Clinical and Translational Research and consisted of a diverse group of statewide community members. The purpose of the board was to provide researchers with guidance in appreciating community values, concerns, and needs. Critical recommendations made by the board for reaching potential participants included two school-based health clinics and several contacts for trusted school-based mentors at high schools in two separate counties included in the study.

3.3. Develop realistic eligibility criteria

With the insight garnered from engaging WIC and the community advisory board, two investigators (AG and BMB) developed participant eligibility criteria, which included adolescent (<20 years) WIC clients who were pregnant or within one-year postpartum. One of the goals of the recruitment study was to describe the sociodemographic characteristics of WIC clients and their coparticipants who opted to enroll in the study; information that would be used in future clinical trial planning. Thus, investigators decided gestational age, race, and ethnicity would not be included as inclusion or exclusion criteria.

In addition to adolescents, one adult coparticipant (≥18 years) was recruited concurrently. An a priori criterion required the coparticipant be a parent or guardian of the adolescent; however, this was later modified to include any adult (i.e., parent, grandparent, sibling, aunt, partner) to allow adolescents of non-parent or guardian households to participate in the study. This decision was made by investigators after encountering eligible adolescent participants who resided with other family members. Adolescent and coparticipant dyads were eligible if

Table 3
Discrete recruitment strategies, actors and principles of partner and community engagement by phase of recruitment.

Recruitment phase and strategy:	Identified by:	Implemented by:	Engagement Principles:
Preplanning:			
1. Identified WIC as a stakeholder and engaged them as community partner with a shared goal (prevent obesity and improve health) and clear purpose (research).	PI; mentors	PI; WIC director	• Long-term commitment • Reciprocity
2. Developed budget with equally allocated resources among partners, PI's effort, participant compensation and research activities. Full budget shared with WIC.	PI; mentors	PI; WIC director	• Partnership and respect • Trust, transparency, honesty
3. Engaged WIC in decision-making, which included identifying opportunities and barriers to recruitment and setting realistic recruitment goals.	PI; mentors	PI; WIC director and providers	• Partnership and respect • Knowledgeable of community
4. Sought WIC providers' perspectives of and experiences with target population. (WIC identified as trusted community resource)	PI	PI; WIC providers	• Mobilizing assets • Knowledgeable of community
5. Met the needs of providers and HD staff by minimizing burden, keeping them informed of HD study visits and supplied with flyers.	WIC director and providers	PI; WIC providers	• Partnership and respect • Flexibility
6. Insight from a research community advisory board; recommended school clinic and trusted school-mentors as partners for outreach and engagement.	CAB	PI	• Knowledgeable of community • Go to community
Outreach and Engagement:			
7. WIC providers engaged adolescents by distributing flyers at required, routine, in-person appointments. (Minimize complexity)	PI; WIC director and providers	WIC providers	• Knowledgeable of community • Go to the community
8. Participants requested to share the study mobile number with other potentially eligible adolescents; word-of-mouth as a means for snowball recruitment.	Participants	Participants; PI	• Collective self-determination • Mobilizing assets (collective agency)
9. Developed a study flyer with information about study activities, compensation and a mobile phone number for convenient contact. (Minimize complexity)	PI; mentors	PI; WIC providers	• Transparency • Collective self-determination
10. Used a mobile phone dedicated to the study for communication with participants. (Minimize complexity and facilitate clear and consistent communication)	PI	PI	• Flexibility • Trust, transparency, honesty
Screening and informing:			
11. Used a simple script to screen participants and provide information about the study via mobile phone. (Clear and consistent communication).	PI	PI	• Clear purpose and goals • Trust, transparency, honesty
12. The PI was transparent about compensation and expectations of participants and PI. (Communication).	PI	PI	• Trust, transparency, honesty • Long-term commitment
Consenting:			
13. In-person verbal description of consent form contents and allowing time for participants to read and ask questions prior to consenting. (Minimize complexity and facilitate communication).	PI	PI	• Trust, transparency, honesty • Go to community
14. Transparent with participants about the study purpose, benefits and minimal risks; the information we needed, how it would be used, kept private and shared. (Minimize complexity and facilitate communication).	PI	PI	• Trust, transparency, honesty • Clear purpose and goals
Enrolling:			
15. Participants were given the option to self-select for a home study visit or a study visit at their county HD. (Minimize complexity)	Participants	PI; participants; HD support for study visits PI	• Go to the community • Flexibility

(*continued on next page*)

Table 3 (*continued*)

Recruitment phase and strategy:	Identified by:	Implemented by:	Engagement Principles:
16. Altruistic adolescent participant (diapers and wipes) and coparticipant (monetary gift card) compensation.	PI; mentors; WIC director and providers		• Knowledgeable of community • Mobilizing assets (altruism)
17. Investigator attributes included being flexible, honest, responsive, trustworthy, and compassionate. (Selecting a research team member with these attributes is a strategic approach to recruitment.)	PI; mentors	PI	• Long-term commitment • Flexibility
Retaining:			
18. Study visits occurred within 10 days of mobile contact with the PI.	PI; WIC providers	PI; HD support for study visits	• Flexibility • Go to the community
19. Pregnant adolescents contacted PI in postpartum if they were interested in completing a postpartum survey (passive retention).	PI	Participants	• Trust, transparency, honesty • Partnership and respect
20. Convenient and minimally burdensome participation for WIC providers, adolescents and their coparticipant.	PI; WIC providers; participants	PI	• Long-term commitment • Flexibility

Abbreviations: WIC, Special Supplemental Nutrition Program for Women, Infants and Children; PI, principal investigator; CAB, community advisory board; HD, health department.
Note: Co-investigators who were also the PI's mentor included (coauthors) BMB, SJH, JBM, and MAW.

they cohabitated in the same household and resided within one of 13 Delta Counties (Table 1). Initially, nine counties were included in the recruitment catchment area, but this criterion was later modified by investigators, and agreed upon by WIC, to include an additional four Delta Counties as awareness and interest in the study spread throughout the Region.

When participant recruitment began in 2017, an average 20,039 pregnant or postpartum women were enrolled in WIC statewide [63]. Using estimates provided by the USDA [64], 15% ($n = 3006$) of those women were adolescents (<20 years). Given the previously stated teen birth rate for the Delta Region [57], we approximated the target population to be 730 pregnant or within one-year postpartum adolescent WIC clients across 13 Delta Counties; representing approximately 24.3% of all adolescent WIC clients across all 82 Mississippi counties in 2017. In the context of the target population and study resources (i.e., personnel, time, funding), investigators set a recruitment study goal of 150 adolescent-coparticipant dyads (75 pregnant and 75 postpartum dyads) within a two-year study period.

3.4. Limit protocol complexity to reduce burden of participation

During the planning process, important details emerged that shaped WIC's role in conducting participant recruitment. Namely, if recruitment were to occur through WIC, the WIC director and regional supervisors requested procedures be minimally burdensome, accounting for limited provider time and organizational resources. WIC and the PI agreed it would be feasible for providers to conduct participant outreach by distributing information flyers during regularly scheduled, in-person appointments with adolescent clients, without the responsibility and complexity of screening and enrolling participants. At the request of the PI, county health departments and WIC food distribution centers also agreed to provide the use of private office space for study visits.

To minimize recruitment burden for potential participants, informing and screening potential participants was conducted via text message or phone call. Eligible and interested participants were enrolled by scheduling a study visit, which considered the most convenient day and time for families. To mitigate transportation barriers, families were given the option for their study visit to occur at their home or respective county health department. The PI decided home study visits had to be an option after encountering an adolescent and her aunt walking almost 2 miles in July to the health department to complete a survey. Once given this option, utilization of health department space became infrequent, further minimizing the burden on health department staff.

3.5. Develop a realistic communication budget

The communication budget consisted of four low-cost strategies that were highly effective. Three strategies were identified by the PI in the initial planning process, which were supported by WIC. These strategies included developing and printing a study flyer to facilitate participant engagement; use of a state-issued mobile phone for participant screening and communication; and development and dissemination of an infographic to easily communicate study findings with the WIC community (total cost for these strategies over a two-year study period was approximately $1216). After recruitment began and at the request of participants, the PI agreed to permit families to share the study's mobile number with ither potentially eligible families via word-of-mouth, known as snowball recruitment. This strategy was identified and implemented by study participants and was at no monetary cost to the study.

3.6. Develop an adequate budget and resources for trial feasibility

All research participants received compensation for their time and contributions to the study. The PI designed the compensation plan purposely to ameliorate the costly needs of caring for an infant; each adolescent received 5 cases of diapers (64 to 240 diapers per case; quantity varied by size) and 1 case of wipes (423 wipes per case). Given that the University of Mississippi Medical Center has a hospital for women and infants, diapers and wipes were purchase at a significantly reduced cost (about $17 per participant) but provided adolescents with diapers and wipes retailed at over $125. All coparticipants received a monetary gift card valued at $60. The compensation plan was strongly supported by WIC providers [62] and was well received and highly valued by participants.

To the contrary, project management and data collection required significant investigator resources and monetary cost. The PI was committed to managing the mobile phone and responding to contacts 7 days per week. This included screening and enrolling participants, confirming and rescheduling appointments, responding to birth announcements and gender reveals, and in general, being accessible to participants and engaging in continuous communication. Consistent communication had an essential role in developing trusting and compassionate relationships with families.

When designing the *Teen Mom Study*, investigators anticipated a

significant amount of time would be dedicated to traveling and preparing for study visits. The PI traveled approximately 19,300 miles (over a two-year study period); organized, monitored and delivered 883 cases of diapers and wipes; and spent between 1 and 2.5 h organizing and loading study materials prior to each day of data collection, which included evening hours, weekends, and holidays. The PI was able to conduct up to 4 study visits per day, limited by vehicle space for diapers and wipes and distance. Communities across the 13 Delta Counties were, on average, 135 miles each way. The time and monetary costs for travel were significant, yet invaluable. Meeting participants where they were most comfortable and at locations most convenient for them demonstrated flexibility and commitment and enhanced trust between families and the PI.

Recruitment was conducted between January 2018 and May 2019. Over the 15-month recruitment period there were approximately 2.5 months when data collection was unexpectedly delayed while waiting for diapers and wipes to be shipped and received; a problem that arose as a result of the unanticipated and overwhelming participant interest in the study. With the exception of this time period, participant consent and data collection were most often completed within 10 days of initial contact with the PI. On only two occasions an adolescent and coparticipant missed a scheduled study visit but, in both cases, were rescheduled and completed.

4. Recruitment results

4.1. Study participants

The recruitment goal included 150 adolescent-coparticipant dyads; 96.7% of this goal was achieved including 145 dyads. Adolescent participants represented approximately 19.5% ($n = 142$) of the estimated potential target population (Fig 1). Over a 15-month period, about 25.9% ($n = 189$) of the estimated target population made contact with the PI; however, the exact number of adolescents who opted to not contact the PI was unknown. Among those referred, 91.5% ($n = 173$) were screened and among them, 82.1% (n = 142) were eligible; 31 contacts were ineligible because they were ≥ 20 years-old (n = 14), not enrolled in WIC ($n = 9$) or lived outside the catchment area ($n = 8$). A total of 142 adolescent WIC clients and 139 coparticipants completed the study ($N = 281$).

Among adolescent participants were 61 pregnant and 48 postpartum only survey participants, and 33 participants who completed both a pregnancy and postpartum survey (Table 4). The majority (95%) of all pregnant adolescents were between 15 and < 20 years-old (mean age = 18.3 years); 49% were between 13- and 26.9-weeks' gestation; 87% were Black; and 45% were overweight (25%) or obese (20%) before they became pregnant.

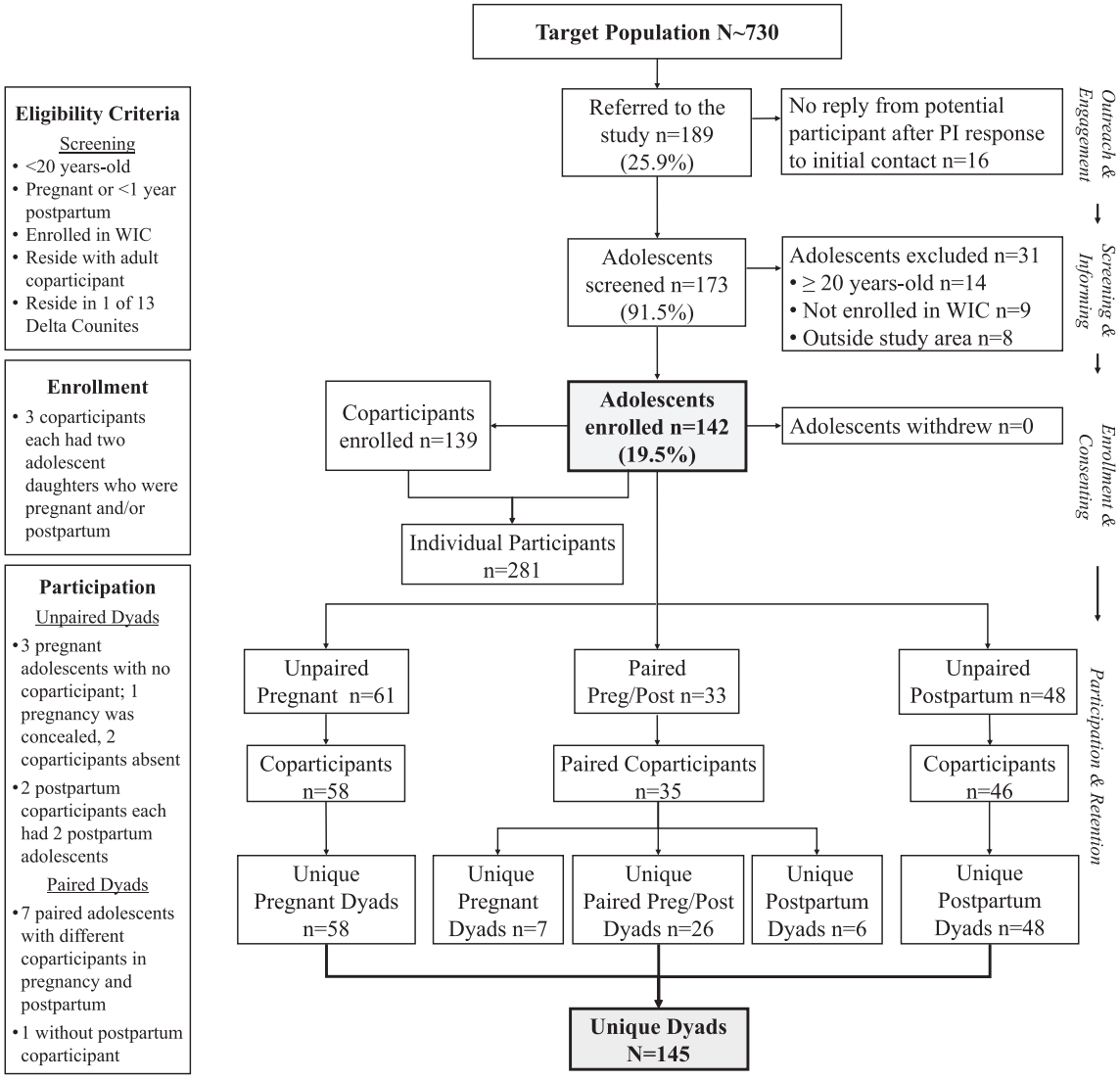

Fig 1. Participant recruitment.

Table 4
Adolescent participant sociodemographic and health characteristics.

	All Teens*	Unpaired Surveys		Paired Surveys (n = 33)	
	(n = 142)	Pregnant (*n* = 61)	Postpartum (*n* = 48)	Pregnant	Postpartum
Age at visit, years	18.35 (1.48)	18.18 (1.44)	18.52 (1.77)	18.42 (1.03)	18.91 (0.94)
Age at visit, 15 – <20 years	129 (91%)	55 (90%)	41 (85%)	33 (100%)	31 (94%)
Age at conception, years	17.68 (1.49)	17.75 (1.43)	17.41 (1.80)	17.96 (0.98)	–
Age at delivery, years	18.18 (1.80)	–	18.18 (1.80)	–	18.67 (0.95)
Gestational age, weeks	23.18 (8.91)	22.76 (8.92)	–	23.96 (8.97)	–
First trimester, ≤ 12.9 weeks	14 (15%)	10 (16%)	–	4 (12%)	–
Second trimester, 13–26.9 weeks	49 (52%)	34 (56%)	–	15 (45%)	–
Third trimester, ≥ 27 weeks	31 (33%)	17 (28%)	–	14 (42%)	–
Gestational age, ≤ 16 weeks	26 (28%)	19 (31%)	–	7 (21%)	–
Postpartum, weeks	18.02 (19.34)	–	18.02 (19.34)	–	12.13 (12.99)
Subacute, ≤ 6.9 weeks	17 (35%)	–	17 (35%)	–	16 (48%)
Delayed, 7–26.9 weeks	17 (35%)	–	17 (35%)	–	14 (42%)
Later, ≥ 27 weeks	14 (29%)	–	14 (29%)	–	3 (9%)
Parity					
0 Children	76 (54%)	46 (75%)	0 (0%)	30 (91%)	0 (0%)
1 Child	52 (37%)	13 (21%)	39 (81%)	0 (0%)	30 (91%)
2 Children	13 (9%)	2 (3%)	8 (17%)	3 (9%)	0 (0%)
3 Children	1 (1%)	0 (0%)	1 (2%)	0 (0%)	3 (9%)
Race, Black	124 (87%)	54 (89%)	42 (88%)	28 (85%)	28 (85%)
Single, never married	142 (100%)	61 (100%)	48 (100%)	33 (100%)	33 (100%)
Education					
Middle school	10 (7%)	7 (11%)	2 (4%)	1 (3%)	1 (3%)
Some high school	66 (46%)	27 (44%)	24 (50%)	15 (45%)	11 (33%)
High school or GED	50 (35%)	21 (34%)	15 (31%)	14 (42%)	16 (48%)
Some college	15 (11%)	5 (8%)	7 (15%)	3 (9%)	5 (15%)
College degree	1 (1%)	1 (2%)	0 (0%)	0 (0%)	0 (0%)
Employment					
Unemployed	114 (80%)	50 (82%)	38 (79%)	26 (79%)	25 (76%)
Part-time	22 (15%)	8 (13%)	8 (17%)	6 (18%)	5 (15%)
Full-time	3 (2%)	1 (2%)	1 (2%)	1 (3%)	3 (9%)
Disabled	3 (2%)	2 (3%)	1 (2%)	0 (0%)	0 (0%)
Heath insurance					
Public only	117 (88%)	46 (84%)	41 (89%)	30 (94%)	27 (87%)
Private only	9 (7%)	5 (9%)	3 (7%)	1 (3%)	1 (3%)
Both public and private	2 (2%)	1 (2%)	1 (2%)	0 (0%)	0 (0%)
None	5 (4%)	3 (5%)	1 (2%)	1 (3%)	3 (10%)
Perceived health status					
Poor	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Fair	21 (15%)	5 (8%)	13 (27%)	3 (9%)	6 (18%)
Good	54 (38%)	20 (33%)	16 (33%)	18 (55%)	15 (45%)
Very good	41 (29%)	24 (39%)	11 (23%)	6 (18%)	8 (24%)
Excellent	26 (18%)	12 (20%)	8 (17%)	6 (18%)	4 (12%)
Been told by a doctor NOT to exercise	4 (3%)	0 (0%)	2 (4%)	2 (6%)	1 (3%)
Self-reported ≥1 chronic condition	27 (19%)	7 (11%)	15 (31%)	5 (15%)	11 (33%)
Type 1 diabetes	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Type 2 diabetes	2 (1%)	0 (0%)	1 (2%)	1 (3%)	1 (3%)
Gestational diabetes	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (6%)
Preeclampsia	5 (4%)	0 (0%)	4 (8%)	1 (3%)	4 (12%)
Hypertension	4 (3%)	1 (2%)	2 (4%)	1 (3%)	2 (6%)
Hyperlipidemia	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Asthma	20 (14%)	7 (11%)	10 (21%)	3 (9%)	3 (9%)
Postpartum Depression	1 (1%)	0 (0%)	1 (2%)	0 (0%)	3 (9%)
Pre-pregnancy BMI					
Underweight	5 (4%)	4 (7%)	1 (2%)	0 (0%)	0 (0%)
Normal weight	71 (50%)	28 (46%)	24 (50%)	19 (58%)	18 (55%)
Overweight	33 (23%)	16 (26%)	9 (19%)	8 (24%)	9 (27%)
Obese	33 (23%)	13 (21%)	14 (29%)	6 (18%)	6 (18%)

Cells presented as: mean (sd) or n (%)
*Participants who completed both a pregnant and postpartum survey are included only once using the pregnancy survey

The majority of coparticipants were the adolescents' mother (72%; mean age = 40.7 years) and among them, 87% were overweight (14%) or obese (73%) and 43% self-reported having one or more chronic condition including type 2 diabetes (15%), hypertension (28%) and asthma (13%). Characteristics of all coparticipants are presented in Table 5 and adolescent-mother dyad characteristics were explored separately and presented in Table 6.

A total of 145 unique adolescent-coparticipant dyads completed the study (94.6% of the recruitment goal), including 58 pregnant and 46 postpartum survey dyads; 26 dyads completed both a pregnancy and postpartum survey; and seven pregnant and six postpartum adolescents completed both surveys, but had different coparticipants for each respective survey, while one adolescent had no coparticipant in postpartum. Among those eligible ($n = 74$) to complete both a pregnancy and postpartum survey, 45% ($n = 33$) self-selected to complete a postpartum survey.

4.2. Recruitment sites

Flyers were made available to WIC providers at nine county health

Table 5
Coparticipant sociodemographic and health characteristics.

	All parents ($n = 139$)	Mother ($n = 100$)	Grandmother ($n = 12$)	Other ($n = 27$)
Age at visit, years	40.11 (9.53)	40.70 (4.78)	58.35 (11.21)	29.83 (8.76)
Age at delivery, years	–	22.50 (5.04)	–	–
Sex, female	130 (94%)	100 (100%)	12 (100%)	18 (67%)
Parity	3.12 (1.39)	3.40 (1.05)	3.83 (1.47)	1.78 (1.65)
Race, Black	118 (87%)	87 (88%)	10 (91%)	21 (81%)
Marital status				
Single, never married	85 (61%)	58 (58%)	5 (42%)	22 (81%)
Married	32 (23%)	24 (24%)	3 (25%)	5 (19%)
Divorced	10 (7%)	9 (9%)	1 (8%)	0 (0%)
Separated	10 (7%)	8 (8%)	2 (17%)	0 (0%)
Widowed	2 (1%)	1 (1%)	1 (8%)	0 (0%)
Education				
Middle school	2 (1%)	0 (0%)	2 (17%)	0 (0%)
Some high school	18 (13%)	9 (9%)	2 (17%)	7 (26%)
High school or GED	59 (42%)	44 (44%)	4 (33%)	11 (41%)
Some college	40 (29%)	32 (32%)	1 (8%)	7 (26%)
College degree	20 (14%)	15 (15%)	3 (25%)	2 (7%)
Employment				
Unemployed	36 (26%)	18 (18%)	5 (42%)	13 (48%)
Part-time	22 (16%)	15 (15%)	3 (25%)	4 (15%)
Full-time	55 (40%)	48 (48%)	0 (0%)	7 (26%)
Disabled	25 (18%)	19 (19%)	3 (25%)	3 (11%)
Retired	1 (1%)	0 (0%)	1 (8%)	0 (0%)
Heath insurance				
Public only	64 (47%)	44 (44%)	9 (75%)	11 (46%)
Private only	39 (29%)	32 (32%)	3 (25%)	4 (17%)
Both public and private	1 (1%)	1 (1%)	0 (0%)	0 (0%)
None	32 (24%)	23 (23%)	0 (0%)	9 (38%)
Household receiving SNAP benefits	91 (67%)	67 (67%)	7 (58%)	17 (74%)
Perceived health status				
Poor	9 (6%)	7 (7%)	0 (0%)	2 (7%)
Fair	36 (26%)	25 (25%)	5 (42%)	6 (22%)
Good	62 (45%)	47 (47%)	3 (25%)	12 (44%)
Very good	25 (18%)	16 (16%)	4 (33%)	5 (19%)
Excellent	7 (5%)	5 (5%)	0 (0%)	2 (7%)
Been told by a doctor NOT to exercise	5 (4%)	4 (4%)	0 (0%)	1 (4%)
Self-reported ≥1 chronic condition	65 (47%)	43 (43%)	11 (92%)	11 (41%)
Type 1 diabetes	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Type 2 diabetes	24 (17%)	15 (15%)	6 (50%)	3 (11%)
Gestational diabetes	5 (4%)	4 (4%)	0 (0%)	1 (4%)
Preeclampsia	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Hypertension	37 (27%)	28 (28%)	6 (50%)	3 (11%)
Hyperlipidemia	10 (7%)	5 (5%)	3 (25%)	2 (7%)
Asthma	19 (14%)	13 (13%)	0 (0%)	6 (22%)
Body Mass Index				
Underweight	1 (1%)	0 (0%)	0 (0%)	1 (4%)
Normal weight	20 (14%)	13 (13%)	0 (0%)	7 (26%)
Overweight	19 (14%)	14 (14%)	3 (25%)	2 (7%)
Obese	99 (71%)	73 (73%)	9 (75%)	17 (63%)

Cells presented as: mean (sd) or n (%)
Note: Coparticipants who completed both a pregnant and postpartum survey are included only once using the pregnancy survey

departments (69.2%) within the 13-County catchment area, one WIC food distribution center in each of three counties, and two school health clinics in each of two counties. Overall, most participants were referred to the study via participant word-of-mouth (51.4%) or WIC provider (43%). Table 7 reports participant recruitment statistics by recruitment method and county.

5. Discussion

Recruitment is a key component to designing clinical trials with health disparity populations historically underrepresented in health research. Investigators anticipated participant recruitment among a predominantly Black, perinatal adolescent population in a socioeconomically disadvantaged rural region of Mississippi would be challenging. To the contrary, investigators were happily surprised by the overwhelming interest and study participation, and believed recruitment success to have resulted from adopting a structured, community-centered approach to recruitment planning. In particular, there were four important aspects of recruitment planning that emerged from using the CTTI framework, which are discussed as follows:

Establishing partnerships with trusted community resources is a paramount investment. Appropriately, a recurring CTTI recommendation is to partner with stakeholders and engage them in designing and planning for clinical trials. In the Mississippi Delta, WIC is regarded by expectant mothers and families with young children as an important community resource, and WIC providers recognize the importance of understanding the needs, values and cultures of the clients they serve [62]. Developing a robust recruitment protocol including passive recruitment strategies was feasible because of the partnership with WIC and their position within the community. An essential mechanism of success came from WIC initiating participant engagement by simply distributing an information flyer. The impact of this partnership will improve the feasibility and effectiveness of future clinical trials and importantly, contributes to the representation of a health disparity population in health research.

Furthermore, too often, lip service is paid to the enormous investment of resources needed for effective partnership development. The experiences described above demonstrate what it truly takes to bring the CTTI recommendations for stakeholder and partner engagement to life and highlights the utility of the PCOR and CTSA principles of partner and community engagement. The partnership with WIC was initiated three years prior to beginning participant recruitment and included collaboration with three different WIC directors. This partnership was fruitful and sustainable because investigators dedicated significant time to building relationships and were responsive to partner needs, which in some instances increased burden on investigators. For early career faculty with a community-based research agenda, this investment may hinder other forms of scholarly productivity (i.e., peer-reviewed manuscripts, grant applications) commonly used as metrics for faculty evaluation and advancement. The amount of time needed to forge organizational and community partnerships in research needs to be acknowledged and appreciated, which should be reflected in the tenure and promotion criteria for these faculty to be successful.

Dedicating time and resources to know and go to your community is invaluable. Another important CTTI recommendation that is echoed by the CTSA principles of community engagement is, be familiar with the target population and identify where they seek treatment and relevant information. Following this recommendation fortified a successful protocol comprised of passive recruitment strategies. The time spent in and with the WIC community fostered a familiarity of the social and cultural dynamics of the Delta Region, which led investigators to leverage the prominent cultural characteristics of altruism and collective agency common within communities of color [17,62]. In Mississippi, collective agency is known to be especially valued among rural, close-knit communities where family, friends, and neighbors are sought after and trusted sources of information [62]. This was demonstrated by families' requests to share study information via word-of-mouth, which contributed substantially to participant recruitment. Word-of-mouth has been reported as an effective strategy in research with minority and disadvantaged communities [65–67] and in particular, was a valued sociocultural strategy for recruiting Black families with obese adolescents in a weight loss intervention study [68].

Furthermore, the sharing of study information via word-of-mouth to family, friends and community members was a clear demonstration of

Table 6
Adolescent-mother dyad sociodemographic and health characteristics.

	Pregnant Dyads ($n = 44$)		Postpartum Dyads ($n = 56$)	
	Adolescent	Mother	Adolescent	Mother
Age at visit, years	17.88 (1.47)	40.30 (5.35)	18.64 (1.54)	41.27 (4.35)
Age at visit 15 - <20 years	40 (91%)	–	49 (88%)	–
Age at delivery, years	–	22.43 (5.68)	18.34 (1.56)	22.63 (4.50)
Gestation, ≤ 16 weeks	14 (32%)	–	–	–
Parity				
0 Children	38 (86%)	0 (0%)	0 (0%)	0 (0%)
1 Child	5 (11%)	1 (2%)	48 (86%)	1 (2%)
2 Children	1 (2%)	7 (16%)	5 (9%)	11 (20%)
3 Children	0 (0%)	15 (34%)	3 (5%)	23 (41%)
4 Children	0 (0%)	10 (23%)	0 (0%)	14 (25%)
≥ 5 Children	0 (0%)	11 (25%)	0 (0%)	7 (13%)
Race, Black	40 (91%)	40 (91%)	48 (86%)	47 (85%)
Single, never married	44 (100%)	24 (55%)	56 (100%)	35 (63%)
Education				
Middle school	7 (16%)	0 (0%)	2 (4%)	0 (0%)
Some high school	20 (45%)	3 (7%)	24 (43%)	6 (11%)
High school or GED	15 (34%)	21 (48%)	22 (39%)	24 (43%)
Some college	2 (5%)	14 (32%)	8 (14%)	17 (30%)
College degree	0 (0%)	6 (14%)	0 (0%)	9 (16%)
Employment				
Unemployed	38 (86%)	7 (16%)	42 (75%)	9 (16%)
Part-time	4 (9%)	7 (16%)	10 (18%)	11 (20%)
Full-time	1 (2%)	22 (50%)	3 (5%)	26 (46%)
Disabled	1 (2%)	8 (18%)	1 (2%)	10 (18%)
Perceived health status				
Poor	0 (0%)	2 (5%)	0 (0%)	6 (11%)
Fair	2 (5%)	11 (25%)	15 (27%)	15 (27%)
Good	14 (32%)	21 (48%)	21 (38%)	21 (38%)
Very good	20 (45%)	8 (18%)	12 (21%)	12 (21%)
Excellent	8 (18%)	2 (5%)	8 (14%)	2 (4%)
Been told by a doctor NOT to exercise	0 (0%)	1 (2%)	3 (5%)	4 (7%)
Self-reported ≥1 chronic condition	5 (11%)	22 (50%)	21 (38%)	19 (34%)
Type 1 diabetes	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Type 2 diabetes	0 (0%)	4 (9%)	2 (4%)	11 (20%)
Gestational diabetes	0 (0%)	0 (0%)	2 (4%)	2 (4%)
Preeclampsia	0 (0%)	0 (0%)	6 (11%)	0 (0%)
Hypertension	0 (0%)	15 (34%)	3 (5%)	11 (20%)
Hyperlipidemia	0 (0%)	1 (2%)	0 (0%)	3 (5%)
Asthma	5 (11%)	8 (18%)	10 (18%)	3 (5%)
Weight status*				
Underweight	4 (9%)	0 (0%)	1 (2%)	0 (0%)
Normal weight	24 (55%)	7 (16%)	28 (50%)	6 (11%)
Overweight	10 (23%)	10 (23%)	13 (23%)	3 (5%)
Obese	6 (14%)	27 (61%)	14 (25%)	47 (84%)

Cells presented as: mean (sd) or n (%)
Note: Adolescent-mother dyads who completed both a pregnancy and postpartum survey are included as postpartum only.
* Adolescents' pre-pregnancy weight status.

Table 7
Engagement strategies across study catchment area.

	Study Flyers			Participant Word-of-Mouth	
County	WIC Provider/ CHD	WIC Distribution Center	School Health Clinic		Participants per county
A	9	–	–	11	20 (14%)
B	2	–	–	8	10 (7%)
C	3	1	–	1	5 (4%)
D	–	–	–	0	0 (0%)
E/F	2	–	3	1	6 (4%)
G	13	–	–	6	19 (13%)
H	16	2	–	4	22 (16%)
I	2	–	–	2	4 (3%)
J	–	–	–	5	5 (4%)
K	–	–	–	13	13 (9%)
L	0	0	2	0	2 (1%)
M	14	–	–	22	36 (25%)
Participants per source	61 (43%)	3 (2.1%)	5 (3.5%)	73 (51.4%)	142

Abbreviation: CHD, county health department.
Notes: County names are blinded to maintain participant anonymity. Counties E/F share one health department.

trust. The PI was a White, New Jersey native and at the time of the study, approaching middle-age with no children of her own. She was, at first, a stranger. She looked and sounded different yet was welcomed into the homes of Delta families. Once the expectations and promises made to participants by the PI were fulfilled, participants not only shared study information, but sent the message that this person could be trusted. This message alone was an important finding and huge success.

In addition, the influence of familial altruism became apparent as a significant motivator for parental (predominantly mothers) engagement resulting in adolescent participation, which may have circumvented previously reported parental consent barriers to research with adolescent populations [38,39] and served as a mechanism for success. Provision of diapers and wipes as compensation for adolescent research participation also had altruistic value among families. Black families in poverty commonly dwell in multigenerational, female-head-of-households [69], a characterization of many Delta families that is reflected in the sociodemographic characterization of our study sample. Compensating adolescent participants with diapers and wipes had altruistic value by meeting household needs and fulfilling the shared goal and responsibility of caring for an infant. The monetary compensation for coparticipants is believed to have had altruistic value as well; many mothers of pregnant adolescents commented on using the gift card to purchase items for the baby such as car seats. While coersion is important to consider in research with vulnerable populations, this compensation, with input from WIC, was appropriate for the time that families spent in study activities.

Our participants taught us that developing an adequate budget for meaningful and valued compensation and dedicating resources to become familiar with the community, and for the community to become familiar with researchers, is important. Allocating monetary resources and time for travel to meet participants at their home or respective county health department mitigated transportation barriers, enabled opportunities to connect with the community, demonstrated respect for participant needs, and fostered trust between participants and the PI. Having institutional support (i.e., department chairs, deans, mentors) and grant funding were important attributes that enabled the PI to spend time in and with the community. For investigators of academic medical centers, a wise endeavor may be to explore opportunities to purchase items for compensation that may be available at reduced cost and that have altruistic value among potential participants.

Offering convenient, continuous and clear communication fosters trust. Identifying appropriate channels for sharing information and disseminating messages enabled investigators to have continuous communication with participants, which kept them engaged in the recruitment and enrollment processes. The communication budget for this study was minimal, but importantly, provided convenient, continuous and clear communication between participants and the PI; integral components for establishing trust and providing transparency. In addition to communicating information to potential participants through WIC and by word-of-mouth, utilizing a password protected mobile phone dedicated to the study and managed 7 days per week contributed to recruitment success and enabled investigators to monitor recruitment metrics. The PI was able to determine the number of contacts made and the outcomes of eligibility screening and reasons for exclusion. Thus, another recommendation for investigators is to explore the option of a state-issued mobile phone and identify a member of the research team who is willing and able to continuously monitor communication.

Limiting partner and participant burden encourages collaboration and participation. In a review of recruitment strategies from 17 randomized controlled trials with minority and underserved populations, studies that reported having implemented strategies to minimize participant burden resulted in favorable recruitment [5]. As part of the commitment to establishing organizational and community partnerships, the role of WIC providers and expectations of adolescent WIC clients and their families had to be minimally burdensome. While the research team and WIC providers and participants shared the same goal, to isupport the health and wellbeing of *all* children in Mississippi, investigators had to be responsive to partners' needs, limitations and expectations. Investigators embraced bearing the brunt of the work needed to bring these partnerships to fruition and successfully recruit adolescents and their families. This team is well-positioned to begin recruitment for intervention trials aimed to reduce disparities in obesity among a vulnerabl and understudied perinatal population.

5.1. Limitations

While we were limited in our ability to understand all of the mechanisms underlying our recruitment, in planned future work, the investigative team will develop appropriate milestones and metrics [70] to monitor recruitment and use qualitative methods to uncover mechanisms yielding desired recruitment effects. A potential limitation to the current study may be the potential for limited generalizability of findings due to the focus on predominantly Black WIC families in the Mississippi Delta; however, evidence from the scientific literature suggests most strategies in varying combinations and intensities have been successful with other minority and disadvantaged populations in the U.S. [17,41–44]

6. Conclusions

Establishing successful, sustainable and fruitful organizational and community partnership requires a substantial amount of invaluable time and fosters recruitment success. Following the CTTI framework and recommendations for recruitment planning led to a robust recruitment protocol that will be used in future intervention studies with perinatal adolescents at high risk for obesity. Use of passive recruitment strategies grounded in principles of partner and community engagement resulted in an effective multicomponent protocol that was flexible, accommodating, altruistic, community-focused, and minimally burdensome to partners and participants. Investigators demonstrated the feasibility of recruiting a disadvantaged and vulnerable perinatal adolescent population that is underrepresented in health research, in one of the most persistently impoverished and poor health regions in the U.S. The systematic and comprehensive reporting of the recruitment planning process contributes to addressing a gap in the literature calling for thorough reporting of recruitment protocols in health research. Authors recommend following the CTTI framework early in the clinical trial development process and closely adhering to the principles of partner and community engagement.

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Declaration of Competing Interest

The authors have indicated that they have no conflicts to disclose.

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