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Benefits and barriers to participating in longitudinal research of youth-onset type 2 diabetes: results from the TODAY retention survey

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Abstract

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Declaration of Conflicting Interests

NWA and MG are paid consultants for a Daiichi-Sankyo pharmaceutical company-sponsored clinical trial. None of the other authors has a conflict to disclose.

Background/Aims—Conducting longitudinal research related to chronic illness in adolescents is inherently challenging due to developmental changes and psychosocial stressors. Participants in the Treatment Options for type 2 Diabetes in Adolescents and Youth (TODAY) clinical trial were socio-economically disadvantaged as well. This study assessed attitudes and beliefs about retention in TODAY to shed light on the factors that potentially promote and detract from the likelihood of sustained participation.

Methods—After an average 7.3 years of follow-up (range 4.9-9.5), TODAY participants completed a survey examining their perceptions of the benefits and barriers to sustained involvement in the protocol.

Results—The most common reasons for staying in TODAY included having a strong relationship with the medical team, getting study-provided diabetes care, access to free diabetes medicine and supplies, and being part of a large study to learn more about how to care for youth-onset type 2 diabetes. The most commonly endorsed challenges included scheduling conflicts, possibly disappointing others, difficulties getting to study visits, and the occurrence of other medical issues.

Conclusions—Similar to other published reports, a supportive relationship with study staff was commonly endorsed as a benefit of engagement in the longitudinal study, suggesting that rapport, staff consistency, and relationship quality are important components of optimal retention. Moreover, our findings suggest the value of trying to remove logistical barriers, such as transportation and scheduling challenges, in order to promote long-term participation in research. Further research is recommended to evaluate factors that contribute to attrition versus retention in an *a priori* manner within longitudinal studies, especially protocols involving cohorts that are more vulnerable to attrition due to developmental transitions and/or socio-economic challenges. Additional efforts to optimize quantitative and qualitative measurement of barriers would also help to expand our understanding of how to optimally retain participants in longitudinal protocols.

Keywords

Retention; type 2 diabetes; adolescents; underserved minorities; longitudinal follow-up

Introduction

With the rise in childhood obesity, youth-onset type 2 diabetes has become an increasing public health concern. Treatment Options for type 2 Diabetes in Adolescents and Youth (TODAY) was the first randomized clinical trial comparing treatments for youth-onset type 2 diabetes. The TODAY study compared metformin monotherapy with two additional combination therapies to examine the hypothesis that combination therapy would accomplish more sustained glycemic control than monotherapy. The methods and primary findings of TODAY have been reported.^{1,2} At the end of experimental intervention during TODAY in 2011, study participants (2-6.5 years of follow-up) were invited to transition into the post-intervention phase called TODAY2 that continued to offer standard diabetes and related medical care from the 15 clinical centers, without assignment to differential treatment groups.

Despite widespread efforts to include underserved racial/ethnic minorities in clinical research, cultural, communication and socioeconomic barriers to recruitment and retention remain problematic.³ In preparation for extending long-term observational follow-up in TODAY2, a retention survey was administered to assess perceived benefits and barriers to continuing involvement. This paper summarizes the survey findings with recommendations for optimizing retention in this study population composed primarily of racial-ethnic minorities from families with relatively low socioeconomic status.⁴

Methods

Participants completed a self-report retention survey using a web-based interface inaccessible to site staff in order to mitigate response bias.⁵ Items and instructions were carefully worded for comprehension by the target cohort to avoid the need to seek clarification from study staff and to preserve privacy.

The retention survey listed nine “reasons for” and nine “problems with” staying in the TODAY study and asked respondents to indicate how much they agreed or disagreed with each statement using a four point Likert-type scale. Participants could submit free text responses. Statistical analyses produced frequency distributions of responses and compared completers and noncompleters using chi-square tests (SAS PROC FREQ, SAS Institute Inc., Cary NC).

Results

Of 699 TODAY participants, 546 (78%) were still active in the first years of TODAY2 and were asked to participate. Of those, 337 (62% of active participants, 48.2% of total TODAY participants) completed a retention survey after an average of 7.3 years of follow-up (range 4.9-9.5). The sample was: mean age 13.8 (SD=2.0) years; 64.7% female; 32.3% non-Hispanic Black, 42.1% Hispanic, 19.9% non-Hispanic White, and 5.6% other racial-ethnic group; 43.5% reporting total household annual income <\$25,000 at baseline; 55.3% reporting household highest education level was high school or less at baseline. Survey respondents were not different from nonresponders by sex, race-ethnicity, randomized treatment group, or failure to maintain glycemic control on treatment during TODAY.

There was fairly uniform agreement with the stated reasons for staying in TODAY (see Table 1). The four statements for staying in the TODAY study the highest level of agreement were essentially indistinguishable (1) having a strong relationship with the medical team (99.1%), (2) getting care for diabetes (98.5%), (3) being part of a large study to learn more about diabetes and help others (97.3%), and (4) getting diabetes medicine and supplies at no cost (96.2%). Only one of the nine items was rated agree or strongly agree by <90%, and it was related to financial remuneration for coming to TODAY visits. The 92 write-in answers did not yield any new categories, but emphasized the importance of the relationship with the study team, direct health benefits, quality of the study, and benefit of helping others.

In terms of perceived problems to staying in TODAY, items with at least 10% agree or strongly agree were: (1) scheduling conflicts with school, work, or family responsibilities;

(2) possibly disappointing the TODAY study team, family, or friends; (3) difficulty attending visits due to transportation, length of visit, or weather; and (4) medical problems other than diabetes. Less than 5% had difficulty interacting with TODAY study staff or had lost interest in TODAY. The 10 write-in responses raised no new points.

Discussion

Conducting longitudinal research in adolescents with chronic illness, developmental transitions, and psychosocial stressors poses many challenges. Successful recruitment and sustained retention are the cornerstones to meaningful clinical research. The TODAY cohort was surveyed about reasons for and against staying in the study 5 to 9 years after randomization.

The most highly endorsed reason for continuing from TODAY to TODAY2 was the importance of relationships with study staff, as has been reported previously in the retention literature. An examination of predictors of engagement and retention in an HIV-prevention intervention similarly underscored the importance of relationship quality between facilitators and participants.⁶ Rapport between study staff and participants has also been shown to be influential in retention rates among other high-risk cohorts, such as families followed longitudinally after prenatal substance exposure.⁷ Aside from the quality of the relationship, simply the consistency of research personnel may be important in promoting retention, as suggested by a report that physician continuity within an adolescent smoking cessation trial impacted retention.⁸

Broad generalization of our findings to other research settings is limited by the specific medical, demographic, and psychosocial features of our cohort. Despite being socio-economically challenged, staying in the study to get money for TODAY visits (\$25 for quarterly medical monitoring visits and \$50 for longer outcome data collection visits) was the least commonly endorsed of the nine reasons. This may indicate the relative unimportance of monetary incentives for the TODAY demographic compared to other tangible (e.g., diabetes medicine and supplies) and intangible (e.g., support, flexibility, and helping others) motivations for continuing to participate.

Also of importance to the TODAY cohort was removing logistical barriers in order to make research participation as seamless as possible. In fact, none of the barriers that we proposed was endorsed by a majority and none of the write-in responses identified other barriers, leading us to conclude that either we have not identified what the barriers are or the retained sample does not recognize barriers. Indeed, a main limitation of this analysis was the lack of data from participants lost to follow-up on what issues contributed to their inability to sustain involvement.

The age of participants may also influence retention. The TODAY cohort was 10-17 at randomization and 15-26 when the survey was administered. Whereas rapport and relationships appear influential when working with children, adolescents, and families, other factors may emerge among adults. For instance, an evaluation of the characteristics that contributed to retention in the Diabetes Control and Complications Trial found that access to

cutting-edge evaluations was most important for this study cohort of adults with type 1 diabetes.⁵

While it is informative to learn from those still engaged in the protocol why they stayed invested in participation and what factors might contribute to subsequent attrition risk, more remains to be understood about retention and attrition. It is important to obtain as much objective data as possible, rather than relying on anecdotal impressions, to shape the design and implementation of subsequent research protocols. Ranking the statements for and against participation against one another would have been helpful, but our study staff advised us that participants would likely need assistance interpreting such instructions, and we selected a more straightforward approach to preserve confidentiality during survey completion. Future longitudinal efforts might benefit from incorporating assessment of factors that promote and detract from retention as part of ongoing process evaluation, particularly at the outset of study recruitment in a more predictive manner.

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Materials developed and used for the TODAY standard diabetes education program and the intensive lifestyle intervention program are available to the public at <https://today.bsc.gwu.edu/>.

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Table 1

Frequency of Retention Survey Responses

	Strongly agree	Agree	Disagree	Strongly disagree
Reasons for staying in TODAY (ordered by % Agree + Strongly Agree)				
I have a strong relationship with my TODAY medical team	73.9	25.2	0.9	0.0
I can get care for my diabetes	79.9	18.6	0.9	0.6
I am part of a large study to learn more about diabetes and help others	75.9	21.4	2.4	0.3
I have flexibility in scheduling my TODAY visits	69.8	26.7	3.3	0.3
I get diabetes medicine and supplies at no cost	74.2	22.0	2.7	1.2
I can get medical tests and procedures	67.6	28.3	3.9	0.3
I have the support and encouragement of family and friends	62.9	32.3	3.9	0.9
I stay motivated to take care of my diabetes	55.1	39.8	4.8	0.3
I get money for coming to TODAY visits	49.3	37.7	7.1	5.9
Problems staying in TODAY (ordered by % Disagree + Strongly Disagree)				
I have difficulty interacting with the TODAY study staff	1.2	0.9	30.9	67.1
I have lost interest in TODAY	0.9	2.9	32.1	64.6
I am not interested in talking or thinking about my diabetes	1.8	3.6	33.2	61.4
Other activities and goals are more important or interesting to me than taking care of my diabetes	1.8	5.1	38.5	54.6
There are too many measurements, tests, procedures, and forms	1.5	8.0	37.8	52.7
I have medical problems to take care of other than my diabetes	4.8	5.7	36.6	53.0
I have difficulty attending TODAY study visits due to problems with transportation, length and time of visits, bad weather, and similar problems	3.3	8.3	42.1	46.3
I might disappoint the TODAY study team, family, or friends	4.8	13.0	34.7	47.4
I have scheduling conflicts with school, work, or family responsibilities	5.6	13.4	42.4	38.6