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Minors' and young adults' experiences of the research consent process in a Phase II safety study of pre-exposure prophylaxis for HIV

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Abstract

Purpose—There is a persistent HIV epidemic among sexual and gender minority adolescents in the U.S. Oral pre-exposure prophylaxis (PrEP) is an efficacious prevention strategy, but not yet approved for minors. Minors' access to biomedical HIV prevention technologies is impeded the ethical and legal complexities of consent to research participation. We explore autonomous consent and study experiences among minor and adult participants in Project PrEPare, a Phase II safety study of PrEP for HIV prevention.

Methods—Data for this mixed-methods descriptive study were collected via self-administered web-survey and in-depth telephone interviews in early 2016. Eligible participants were previously enrolled in Project PrEPare. We attempted to contact 191 participants; 74 were reached and expressed interest in participating, 58 enrolled.

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Results—Participants nearly universally felt well informed, understood the study, and freely volunteered with the clear understanding they could withdraw any time. All felt supported by study staff, but a small minority wished for more support during enrollment. Minors were more likely than adults to indicate a wish for more support in decision-making, and adults expressed higher satisfaction with their decision compared to minors. There was no association between elements of consent and Project PrEPare study outcomes.

Conclusion—Participants had an overwhelmingly positive experience in a Phase II safety study of PrEP for HIV prevention. Some minors wished for more support during the decision making process, but none consulted their parents about the decision. Our results support the inclusion of decisional supports in consent processes for adolescents, while also protecting their privacy.

Keywords

HIV; LGBTQ; prevention; pre-exposure prophylaxis; biomedical ethics; consent

Youth are disproportionately affected by the U.S. HIV epidemic, accounting for an estimated 22% of incident infections.[1] Young men who have sex with men (YMSM) are at especially high risk; approximately 80% of all incident infections among persons aged 13–24 occur in YMSM.[1] Pre-exposure prophylaxis (PrEP) with oral tenofovir-emtricitabine (TDF-FTC) is approved to reduce the risk of sexually acquired HIV-1 in adults.[2, 3] TDF-FTC is not yet approved for PrEP among adolescents younger than 18 years (minor adolescents, henceforth) due to lack of data on its safety, tolerability, and effectiveness in this population.

There is a well-described reluctance to include minors in biomedical HIV prevention research,[4, 5] because doing so presents ethical complexities.[6] In most biomedical research, minor adolescents fall into the category of human subjects whose diminished autonomy requires additional protections, the cornerstone of which is parental permission.[7] However, involving parents in the consent process may force the disclosure of the adolescent's sexual behavior or sexual orientation, which poses risk of social harms.[8] Investigators and institutional review boards (IRBs) must weigh risks of social harm due to disclosure against other risks and benefits of research participation.

The Adolescent Medicine Trials Network for HIV/AIDS Interventions (ATN) faced these ethical complexities directly in Project PrEPare, an open-label, single arm study of PrEP safety and adherence among YMSM and young transwomen.[9] Concerns about disclosure-related vulnerabilities prompted study organizers to allow minors to self-consent; parental permission was not required for enrollment.[9] Project PrEPare was the first biomedical HIV prevention study in the U.S. that allowed minors to autonomously consent for enrollment, where such consent was consistent with local statutes.[9, 10]

Relatively little research examines the relationship between consent processes and the experiences of participants after trial entry.[11] This mixed methods study explores autonomous consent and study experiences among the adolescents and young adults who enrolled in Project PrEPare. We chose a mixed methods design for a more complete picture of the phenomena under study.[12] Our aims were to describe five elements of consent: being informed, understanding the research study, feeling supported, freely volunteering to

enroll, and feeling satisfied with the research experience. A secondary aim was to explore the relationship between age, elements of consent, and Project PrEPare study outcomes (seroconversion, adherence).

Methods

Parent Study, Project PrEPare

Project PrEPare was conducted in two phases. The first phase (ATN 110) enrolled adults aged 18–22 (N=200), and the second phase (ATN 113) enrolled minors aged 15–17 (N=79). Trial results for both protocols are reported elsewhere.[13, 14] Briefly, a majority of participants achieved protective drug levels in the first month on study, but adherence declined thereafter, with rather sharp decreases occurring at week 24. There were a total of 7 seroconversions, which occurred among participants with undetectable or very low drug levels.

Study population

Participants were research subjects in Project PrEPare. They were assigned male sex at birth, and were ages 15 to 22 years, inclusive, when they enrolled in the parent study. A total of 279 YMSM and young transwomen from 12 urban ATN sites (AMTUs) were initially considered eligible. AMTU study staff contacted eligible participants and informed them about our study.

Study Procedures

Quantitative web-based survey—All participants completed a web-based survey to capture demographic data as well as data about participant experiences in Project PrEPare. Likert-type questions about the consent process measured the extent to which the participant felt informed, felt supported during the decision making process, and participated voluntarily. For example: *I am satisfied I was given the information I needed to enroll in the study; I would have liked to have a parent/guardian with me when I made the decision to enroll.* We also evaluated participants' current understanding of research principles, generally, and the purpose of Project PrEPare, specifically, in addition to their experiences of research benefits and harms.

In-depth interview—At the end of the survey, each participant was asked if s/he would be willing to participate in a follow up interview. Interested participants were contacted and interviewed by the first author. Interview questions were designed to elicit in-depth descriptions of consent processes and study experiences. [15] For example: *How capable do you think you were of making the decision to join this study? Is there anything you know now that you wish you had known when you first joined the study?*

Data collection and management

Data were collected from January–April, 2016. Responses were stored on a secure ATN server. Interviews were conducted over the phone or videoconference and audio-recorded with permission. Audio files were transcribed by a professional service. Transcripts were compared to audio files for accuracy.

Data analyses

Quantitative data—Surveys were linked to the following measures from Project PrEPare: age at consent, adherence at week 4 (dried blood spot analyses indicative of at least 4 doses/week), and seroconversion. Data were stripped of identifiers, cleaned, and stored in SPSS. We used descriptive statistics to generate summaries of participants' experiences on study. We constructed two summary measures, one reflecting a desire for support from an adult while making the enrollment decision (2 items, $\alpha=0.73$), and one reflecting satisfaction with decision-making (3 items, $\alpha=0.79$). Due to skewed distributions, we used non-parametric tests to examine age-based differences in study experiences.

Qualitative data—Four members of the research team reviewed the transcripts and interview notes, and collectively discussed their key themes. Together with the study aims, these themes were used to develop an initial set of codes. The transcripts were coded in nVivo software. The first author took primary responsibility for analysis, meeting regularly with three other team members to discuss the coding and data interpretation. [15]

Human Subjects

Study procedures were reviewed and approved by 11 IRBs (see acknowledgements).

Results

We enrolled 58 participants (Figure 1). Fourteen were minors at enrollment in Project PrEPare, and 44 were at least 18 years of age ("adults," henceforth). The age, racial and ethnic composition, and seroconversion rate of our substudy sample and the Project PrEPare sample are similar. All 58 completed the survey, and 44 indicated willingness to be interviewed. We attempted to contact and schedule interviews with all 44 but the number of interviews was limited by time and budgetary constraints. We interviewed 25 participants. To protect their privacy, they are assigned a unique id (I [number]), below.

Time since enrollment in Project PrEPare ranged from 17–37 months (median 31), and time since completing the study ranged from 0–24 months (median: 10). Among participants in this sub-study, adherence at study week four was 66%; there were 2 seroconversions. Aside from age, there were no significant differences in the demographic characteristics (Table 1) of minors compared to young adults. More than two-thirds of participants were persons of color, and 30% were Hispanic or Latino. Slightly more than two-thirds received at least one type of financial aid in their lifetime. The majority (90%) identified as male, and indicated their sexual orientation is "gay" or "queer" (81%).

Description of Participants' Perceptions of Five Elements of Consent

Being Informed—All participants indicated they received the information needed to make the enrollment decision (Table 2). This was reflected in the debriefing interviews. When asked whether there was anything they know now that they wished they had known from the beginning, 22 of the 25 interviewees could not think of anything. Interviewees said they were well informed, and knew exactly what to expect:

“I felt it was perfectly clear. The staff, they were very helpful and the computer [surveys] were very detailed and so I feel like I have a complete understanding of [the study].” I23, minor

Two interviewees identified information they would have liked to know, if it were available: how TDF-FTC would interact with other medications and supplements, and a summary of clinical trial data to date. The third indicated he was confused about the bone density scan when it was time to have that exam; he remembered being told about it, but could not recall why it was necessary.

Understanding the research study—Table 2 indicates the extent to which surveyed participants agreed with a series of statements about research principles. Broadly, their responses reflect the positive experiences they had on study. For instance, 93% of participants indicated agreement that “researchers always try to give each person in a study the care that best meets their individual needs.” Few (10%) indicated it was possible to receive no benefit from participation in the study.

The debriefing interviews provide further insight into the quantitative data. It was clear that all participants understood they were part of a research study. They understood the study goals, which, they described both generically:

“I would say the main point is to prepare you to protect yourself against the STDs that are spreading so widely, which is HIV.” I3, adult

and more precisely:

“They had never done a large scale study in young gay men and they wanted to because we’re the fastest growing demographic for increasing HIV rates...they wanted to see how gay men reacted and if they would actually take PrEP.” I2, minor

At enrollment, interviewees anticipated a variety of benefits, including: extra protection against HIV (n=11), learning more about HIV and safer sex (n=8), frequent testing for HIV and STI (n=5), trying PrEP for free (n=4), financial compensation (n=4), access to good medical care (n=2) and a caring group of adults (n=2), and doing something good for the community (n=2). They also understood potential risks, including: side effects of TDF-FTC (e.g. weight gain, GI upset) (n=8), bone density loss (n=7), renal toxicity (n=4), social stigma if discovered taking an HIV treatment medication (n=4), risk compensation (e.g. more openness to condomless sex) (n=3), and viral resistance to medication (n=1). Five interviewees thought there were no risks, and one said he did not think about the risks.

We also assessed understanding by asking how expectations of the study compared to what was experienced. The interviewees said the study was about as expected (n=11), or better (n=10).

“I thought that I was just going to be a subject with a number...and I would just be given this, and labeled, and do tests. And really, it was an empowering experience in a way...They set a safe, open space where I felt comfortable with myself, I felt proud of myself.” I22, adult

Feeling Supported—Most participants (95%) felt supported by study staff when they enrolled. Half spoke with someone other than study staff prior to enrollment. These 29 participants talked with: a friend (83%), a sexual partner (48%), an adult relative (21%), an older friend (21%), a parent or guardian (17%), or a teacher (10%). Some participants (19%) indicated feeling alone in the decision making process. One minor participant indicated he would have liked to have his parent or guardian present during decision-making, and three non-minors indicated a neutral opinion on this (Table 2). Five participants (9%) would have liked an adult relative, other than a parent or guardian, present to make the enrollment decision; four of these were minors.

The debriefing interviews allowed exploration of participants' perceptions of the need for support during enrollment, regardless of their age at enrollment. Fifteen interviewees (60%; including 2 minors) could not think of anyone they wished would have helped make the decision to enroll; for them, the decision was very personal, and one they felt competent to make:

“I was kind of cool with just me and the doctor. At that time, I also was not out about my identity, so it was kind of like I didn't want to really talk about it.” I13, minor

Two interviewees (8%; both adults) said that it would have been nice to have support at the time of consent; one suggested a best friend and the other said possibly his parents. Other interviewees (n=5) focused less on support and more on persons they definitely would not want present – namely, parents:

“I don't really want to discuss anything with my parents. My dad's on his own agenda...I don't have any contact with [my mother] at all. So I'm pretty much by myself.” I23, minor

All minor interviewees said they either would not have wanted their parents present at enrollment (n=4) or did not feel the need to inform them (n=1).

Mirroring the survey data, about half (n=13) of interviewees spoke with someone about the study before enrolling, most often friends (n=9), followed by partners (n=3), and siblings (n=1). None of the interviewees spoke with a parent or guardian prior to enrollment. Of note, all minors we interviewed eventually discussed participation with their parents. Two minors voluntarily disclosed to parents midway through the study, two disclosed when parents or guardians noticed them traveling frequently (n=2), and one was not sure about the disclosure context. None reported an adverse outcome to the disclosure, but parents'/guardians' reactions were mixed. The two who voluntarily disclosed described generally positive experiences, for example:

“My mom didn't really express any concerns with me doing it, more so it was like I'm proud that you're partaking and staying safe.” (I13, minor)

Among the two whose parents questioned them after noticing travel, reactions were neutral (I7) or positive (I24):

I7: “I told my mom about it because she was like “Why the [expletive] is there a cab outside for you?” ... She did some research on it. When I came home she told me what it was about and I was like ‘I know, mom.’”

Interviewer: “Did she have anything either positive or negative to say about it?”

I7: “No, not really. Since I can remember any decision that I’ve made has really been mine. She can always put in her input, but whatever I wanted to do with myself, that was on me.”

“They were kind of curious to know ‘Why were you heading out to [city in which clinic is located] a lot?’ and so I told them what’s going on and this is what I’m participating in. They were like, ‘Okay’ ... All they understood was it was a medical study. I’ve explained it to them, but they weren’t concerned or anything. I guess anything that’s good they would encourage it.” (I24, minor)

Interviewee 23 was living with his mother during the study period, and she became aware that he was taking the study drug:

Interviewer: “And what did your mom say when she found out?”

I23: “She didn’t really accept it. She didn’t deny me taking it.”

Interviewer: “Do you have any sense for what about it she didn’t accept?”

I23: “She’s really manipulative and controlling, so it was just because I got it by myself, without her permission. She was upset about that more than the social issue of it.”

Interviewee 23 experienced emotional and physical abuse from his parents over the course of his lifetime, but denied experiencing any harm due to disclosure to his parents. He does not have contact with either parent now.

Freely volunteering to participate—Participants felt enrollment was voluntary; 98% indicated the decision to enroll was entirely their choice, and one (I9) indicated this was somewhat true. Interviewee 9 enrolled in the study because his partner suggested it “as a way for us to not have his status be so much of an issue.” None endorsed the statement that they had enrolled even though they did not want to, and none indicated it would look bad to study staff if they did not enroll. One participant indicated it was “somewhat true” that he felt like he was talked into enrolling in the study. This participant (I12) reported during the interview that he enrolled after he learned that his partner had been having unsafe sex with others. The participant was encouraged to enroll by a participating friend.

To better understand the extent to which participants voluntarily enrolled and participated, we asked what they would have done if they felt uncomfortable participating, or wanted to withdraw. All 25 interviewees felt free to withdraw at any time, for any reason. For example:

“I think I would have just let them know I didn’t want to do it...I never felt pressure that I had to stay.” I2, minor

Three interviewees discontinued TDF-FTC: two due to side effects and one because of low perceived HIV risk.

Feeling Satisfied with the Research Experience—All survey participants (100%) indicated satisfaction with their decision to participate. However, five indicated neutrality or disagreement that the decision was the best one for them personally, and three indicated neutrality or disagreement that the decision was consistent with personal values. Four of these five participants were interviewed. One (I7) was a minor who discontinued PrEP due to side effects; when asked about his overall research experience, he said that the main impact was *“that I know that medication is out there and it’s being worked on every day. But that would be about it.”* The other three were adults that reported no harms on study, and nothing about the study caused discomfort or distress. However, Interviewee 6 said that while study participation led to more information about PrEP and safer sex, there was little impact on his life because he was *“never a really sexual person to begin with.”* Interviewee 9 enrolled in the study because his HIV-infected partner suggested it. He said he probably would not have enrolled if he were not in a serodiscordant relationship, but:

“I feel like looking back on it, at the time it was the right decision. I think now that I’m single and testing a lot it’s a good precautionary measure to have on top of condoms and everything else.” I9, adult

Interviewee 8 reflected similarly on the study:

“I think it’s only benefitted me in the long run now that I take PrEP every day. I’m happy I take it. I think overall, it was the right choice.”

We further explored satisfaction with the study experience by asking interviewees to reflect on how the study had affected their lives. The majority expressed a positive, quite specific impact:

“It just helped me build my character up to where I was more focused on my education, and my coursework, and my employment.” I4, adult

Some viewed study participation as broadly life-changing, and were disappointed by study completion:

“Making that specific decision [to participate] made a lifetime of change for me, and I’m very, very glad about that...it really triggered my mind and it really challenged me.” I15, adult

“I was kind of upset that it was over...I would definitely do it again if I had the chance.” I24, minor

Relationship between Age, Consent, and Study Outcomes

There were statistically significant differences between minors and adults on two measures of support – feeling alone in one’s decision-making, and preference for having a non-parental adult present at the time of consent (Table 3). In both cases, minors were more likely than adults to answer affirmatively. Neither summary measure was predictive of seroconversion or drug adherence.

Discussion

Project PrEPare was the first U.S. study to offer PrEP to minor adolescents and is one of two biomedical HIV prevention trials that allowed autonomous consent.[16] Participants nearly universally felt adequately informed and they understood the basic premise of the study. This is consistent with prior research showing that adolescents are capable of understanding the concepts of randomization and placebo, but may need extra time and interaction (e.g. reframing unclear concepts) during consent processes to reduce the potential for therapeutic misconception. [17]

Participants did not distinguish between individually-focused care compared to clinical care provided as part of a clinical trial, largely agreeing “researchers always try to give people the care that fits their individual needs.” In the context of a placebo-controlled trial of a new medication, this may have raised concerns for therapeutic misconception. However, Project PrEPare was a single arm open-label study of a medication with demonstrated effectiveness, so it is reasonable for participants to expect they were getting treatment. Additionally, participants received individualized sexual risk reduction counseling and intensive clinical surveillance, making agreement with a statement about individualization of care more reasonable. Interviews with participants indicated they felt very well cared for by study staff, and the testing and counseling they received was one of the major benefits of this study.

Participants freely volunteered with the clear understanding they could withdraw at any time. A requirement for permission from others – particularly parents – was seen as largely unnecessary and an almost certain barrier to research participation. Our findings add to data showing that for sexual and gender minority youth, disclosure risks often outweigh the potential benefits of participation.[18, 19]

Our findings do not suggest, however, that research decision-making should be a solitary process, for minors or adults. Although participants felt supported by study staff during the consent process, some expressed need for support from others during enrollment. This need for support may be age-related: the mean summary support score was significantly lower among minors compared to young adults. These findings underscore the importance of clarifying the distinction between a voluntary decision and an independent decision.

Gillies & Entwistle [11] argue that in health care contexts, honoring the principle of respect for autonomy has too often resulted in the conflation of a voluntary choice and an independent one, at the risk of isolating participants from decisional supports. Such isolation may lead to negative research experiences and adverse outcomes such as early withdrawal or poor protocol adherence.[11] Further research is needed to identify who should be formally involved in the research consent process for minors considering participation in a biomedical HIV prevention trial; while parents’ authorization is required by regulation and tradition, sexual and gender minority youth in our study and others [18, 19] indicate parental involvement is a potentially non-negotiable barrier to research participation, especially on stigmatized conditions like HIV and sexual health. Our team is currently studying the acceptability of autonomous consent, flexible consent (choice between parent/guardian or an ombudsman), and required parental permission, from the perspectives of behaviorally high-

risk adolescents and parents of adolescents. The prospect of direct participant benefit, coupled with the broader public health benefits of new prevention technologies, suggests the need for new regulatory and ethical pathways to support minor adolescents' participation in biomedical prevention research.

Few studies examine the relationship between the elements of consent and study outcomes. We did not find a significant relationship between two elements of consent (support and satisfaction with decision) and major study outcomes. However, those results should be interpreted with caution for two reasons: the skewed distribution of our data prohibited construction of summary scales for three other elements of consent, and, our sample size may have lacked power to detect differences.

Limitations

There are several limitations to our study that readers should keep in mind. A limited number of AMTUs participated in our study, so experiences presented here may not be representative of all Project PrEPare participants. However, the demographic characteristics of our sample are largely similar to the entire group of Project PrEPare participants. Participants were not randomly sampled, creating the possibility of self-selection bias. We attempted to counter this by reassuring participants their data would be stripped of identifiers and analyzed in aggregate, and that the interviewer was unaffiliated with AMTUs. The interviewer emphasized all opinions and perspectives were valued, therefore interviewees could answer honestly. Finally, we asked participants to comment on procedures and experiences that began as much as 37 months prior, raising the possibility of recall bias. However, we asked questions about their broader impressions of the study and how well informed they felt overall, rather than asking them to recount the consent process in detail.

Conclusion

There is a persistent HIV epidemic among YMSM and transgender women in the U.S. New prevention approaches, like PrEP, may be key to resolving HIV disparities among these youth. Currently, minors' access to new prevention methods is limited by a research infrastructure that presents barriers to their inclusion in the very safety studies necessary for access. Ending the epidemic among youth may require new approaches to biomedical prevention research consent that allows equitable access to potential research benefits and protection from research-related harms.

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Implications and Contribution

Adult HIV prevention interventions may not be effective for adolescents, but ethical and legal issues often prevent minors from participating in HIV research. Adolescents who joined an HIV prevention study without parent permission had a positive experience. Researchers may consider using decisional supports when parents are not involved in research.

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Figure 1.
Recruitment and enrollment from parent study

Table 1

Demographic Characteristics

Demographic Characteristics		
	N	%
Age *	17,25	22 (20,24)
Race #		
<i>White</i>	18	35
<i>Black or African American</i>	26	51
<i>American Indian</i>	1	2
<i>Multiracial</i>	6	12
Ethnicity		
<i>Non-Hispanic or non-Latino</i>	40	70
<i>Hispanic or Latino</i>	17	30
Gender identity		
<i>Male</i>	52	90
<i>Female or transgender</i>	3	5
<i>Genderqueer or androgynous</i>	3	5
Sexual orientation ^		
<i>Straight</i>	1	2
<i>Gay, queer, or same gender loving</i>	47	81
<i>Bisexual</i>	5	9
<i>Trade</i>	1	2
<i>Questioning</i>	1	2
<i>Down Low</i>	2	4
<i>Other</i>		
Types of financial aid received in lifetime		
<i>None</i>	17	29
<i>One type</i>	19	33
<i>Two or more types</i>	22	38

* Range (col 1), median, IQR (col 2);

Column totals <58 reflect missing responses;

^ Question referred to how participant views himself or herself, not how s/he presents to others

Table 2

Perceptions of Consent Process

	N (%)				Minor vs. Adult
	Strongly disagree or disagree	Neither Disagree nor Agree	Agree or Strongly Agree		
Informed					
I received all the information I needed to make the decision to enroll in the study	0	0	58 (100)		
I received too little information to make the decision to enroll in the study	55 (95)	2 (3)	1 (2)		
I am satisfied I received all the information I needed	4 (7)	0	54 (93)		
Supported					
I felt alone in my decision making	36 (62)	11 (19)	11 (19)		*
I would have liked to have a parent/guardian present with me to make the decision about enrolling in the study	54 (93)	3 (5)	1 (2)		
I would have liked to have an adult other than my parent/guardian present with me to make the decision about enrolling in the study	50 (86)	3 (5)	5 (9)		*
I felt well supported by the study staff in making my decision to enroll in the study	1 (2)	2 (3)	55 (95)		
Satisfied					
The decision I made was the best decision for me personally	1 (2)	4 (7)	53 (91)		
I am satisfied that my decision was consistent with my personal values	1 (2)	2 (3)	55 (95)		
I am satisfied with my decision	-	-	58 (100)		
Volunteered					
I am satisfied this was my decision to make	1 (2)	-	57 (98)		
Understood					
	Disagree or mostly disagree	Don't know	Mostly agree or Agree		
The main purpose of research is to benefit the individuals who participate in the study	23 (40)	4 (7)	31 (53)		
Researchers always try to give each person in a study the care that best meets that person's individual needs	1 (2)	3 (5)	54 (93)		
Everyone who participated in the study would benefit from it in some way	-	2 (3)	56 (97)		
It was possible to receive no benefit from participating in this study	44 (76)	8 (14)	6 (10)		
Volunteered					
	Somewhat false	Somewhat true	True		
	False				

	N (%)				Minor vs. Adult
	Strongly disagree or disagree	Neither Disagree nor Agree	Agree or Strongly Agree		
I felt like I was talked into enrolling in the study	54 (93)	1 (2)	-		
It was entirely my choice to enroll in the study	-	1 (2)	57 (98)		
I enrolled in the study even though I did not want to		-	-		
I felt that it would look bad to the study personnel if I did not enroll in the study	58 (100%)	-	-		

* P<0.05; in both cases, minors agreed more strongly with the statement than adults.

Table 3

Summary measures

	Minors Mean (SE)	Non-Minors Mean (SE)	p-value *
Support Scale (Alpha=0.73)			
I would have liked to have a parent/guardian present with me to make the decision about enrolling in the study	4.2 (.26)	4.7 (.09)	0.048
I would have liked to have an adult other than my parent/guardian present with me to make the decision about enrolling in the study			
Satisfaction Scale (Alpha=0.79)			
The decision I made was the best decision for me personally	4.1 (.18)	4.7 (.07)	0.001
I am satisfied that my decision was consistent with my personal values			
I am satisfied with my decision			

* Mann Whitney U test