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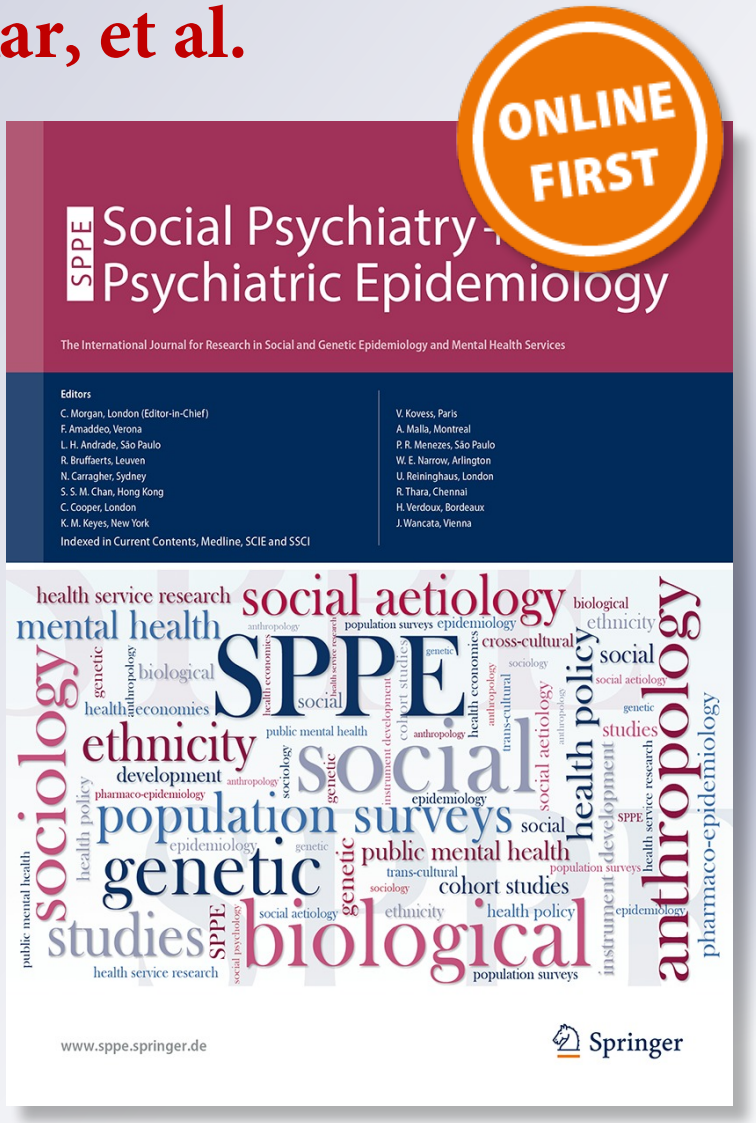

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ORIGINAL PAPER

Customising informed consent procedures for people with schizophrenia in India

Sudipto Chatterjee · Berit Kieselbach · Smita Naik · Shuba Kumar · Sujit John · Madhumitha Balaji · Mirja Koschorke · Hamid Dabholkar · Mathew Varghese · Vikram Patel · Graham Thornicroft · Rangaswamy Thara

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Abstract
Background There is little information on how the ethical and procedural challenges involved in the informed participation of people with schizophrenia in clinical trials are addressed in low- and middle-income countries (LMICs). The informed consent procedure used in the collaborative community care for people with schizophrenia in India (COPSI) RCT was developed keeping these challenges in mind. We describe the feasibility of conducting the procedure from the trial, researcher and participants perspectives and describe the reasons for people consenting to participate in the trial or refusing to do so.
Methods Three sources of information were used to describe the feasibility of the COPSI consent procedure: key process indicators for the trial perspective, data from a specially designed post-interview form for participant's observations and focus group discussion (FGD) with the research interviewers. Categorical data were analysed by calculating frequencies and proportions, while the qualitative data from the FGD, and the reasons for participation or refusal were analysed using a thematic content analysis approach.
Findings 434 people with schizophrenia and their primary caregiver(s) were approached for participation in the

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S. Chatterjee · S. Naik · M. Balaji · V. Patel
Sangath, Goa, India
e-mail: sudipto_dr@yahoo.com.au

S. Naik
e-mail: smitan@sangath.com

M. Balaji
e-mail: madhs@hotmail.com

B. Kieselbach
World Health Organization, Geneva, Switzerland
e-mail: beritkieselbach@gmail.com

S. Kumar
Samarth, Chennai, India
e-mail: shubakumar@samarthngo.org

S. John (✉) · R. Thara
Schizophrenia Research Foundation, Chennai, India
e-mail: Sujitjohn@scarfindia.org

R. Thara
e-mail: thara@scarfindia.org

M. Koschorke · G. Thornicroft
Institute of Psychiatry, Kings' College, London, UK
e-mail: mirja.koschorke@kcl.ac.uk

G. Thornicroft
e-mail: graham.thornicroft@kcl.ac.uk

H. Dabholkar
Parivartan, Satara, India
e-mail: hamid.dabholkar@gmail.com

M. Varghese
National Institute of Mental Health and Neurosciences, Bengaluru, India
e-mail: mat.varg@yahoo.com

V. Patel
London School of Hygiene and Tropical Medicine, London, UK
e-mail: vikram.patel@lshtm.ac.uk

V. Patel · G. Thornicroft
Centre for Global Mental Health, London, UK

V. Patel
Centre for Mental Health, Public Health Foundation of India, New Delhi, India

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trial. Consent interviews were conducted with 332, of whom 303 (91 %) agreed to participate in the trial. Expectation of improvement was the most common reason for agreeing to participate in the trial, while concerns related to the potential disclosure of the illness, especially for women, were an important reason for refusing consent.
Conclusions The COPSI consent procedure demonstrates preliminary, observational information about the feasibility of customising informed consent procedures for people with schizophrenia LMIC contexts. This and other similar innovations need to be refined and rigorously tested to develop evidence-based guidelines for informed consent procedures in such settings.

Keywords Informed consent procedure · Capacity for consent · COPSI trial · Schizophrenia · India

Introduction

People with schizophrenia constitute a vulnerable group who pose specific challenges in relation to their informed participation in clinical trials. One of the key assumptions underlying the informed consent procedure is that the person has adequate decision-making mental capacity to be able to make an informed choice [1]. For people with schizophrenia, decision-making ability is sometimes compromised during some phases of the course of the condition [2, 3]. The most common challenge, therefore, is to ensure that the person with schizophrenia has adequate and specific decision-making ability when choosing whether to participate in a trial or not [4]. As a group, people with schizophrenia tend to perform worse than healthy comparison subjects in terms of understanding of the information related to consent procedures which in part may be related to cognitive impairments in processing, retaining and using the information to make decisions [5]. However, impaired decision-making abilities are not the norm; and more often people with schizophrenia have adequate decisional capacity to give valid consent [6]. Encouragingly, a number of recent studies have demonstrated that the uptake of information can be significantly augmented in people with schizophrenia through simple enhancements in the research consent process [7, 8].

In low-income country settings such as India, there are also additional, contextual challenges that are important to consider when developing consent procedures for randomised clinical trials. Firstly, in comparison to high-income countries, the concept of informed consent is not as uniformly embedded in the medical culture in LMICs like India. Secondly, there are specific concerns in India related to the highly skewed power differential between doctors and potential research participants. Thirdly, information related to the purpose, procedures, risks and potential benefits of trials is often presented in a highly technical manner that is difficult to understand [9]. In addition, in some LMIC settings many potential participants are non-literate and are unable to read the contents of the written information sheets. Fourthly, the close involvement of caregivers in all aspects of decision-making related to accessing treatments in India makes it difficult to ensure 'autonomous' decision making. This has been highlighted in studies conducted in India, these studies [10–12] have reported that it has often been the families' which decide when, where and how the ill relative should be treated with the patients themselves having very little say in the matter. It is also important to keep in mind that this type of 'family decision making' in not exclusive to decisions regarding treatment but cuts across all major domains including decisions regarding marriage, educational choices, vocation choices, etc.

For people with schizophrenia, these concerns are important to address when recruiting participants to RCTs in LMICs. Clinical trials are now universally governed by Good Clinical Practice guidelines [13] that specify the requirements for adequate disclosure of the potential risks and benefits involved, the provision of information in a manner that is understandable to participants, and the requirement for involving an independent witness for those who cannot read. However, there is a marked paucity of information in LMICs on how such complex ethical and procedural challenges are addressed in clinical trials in these settings [14–17].

The community care for people with schizophrenia in India (COPSI) randomised controlled trial (ISRCTN 56877013) was designed to compare the clinical and cost effectiveness of usual, facility-based care (FBC) with a collaborative community-based care (CCBC) intervention that involved FBC combined with a structured psychosocial intervention, delivered by trained community health workers (CHWs). Full details of the trial protocol and main findings are published elsewhere [18, 19]. The trial involved the recruitment of people with schizophrenia who were moderately–severely affected by the illness; as a pre requisite for participation, both the person with schizophrenia and the primary care giver had to provide informed consent prior to their entry into the study. The COPSI informed consent procedure was systematically designed to address these universal and local challenges within the constraints of the trial requirements. Did the COPSI consent procedure work for participants, the researchers who conducted the procedure and from a trial perspective? This is what we describe in the subsequent sections of the paper.

Development and description of the consent procedure

In the COPSI trial, one study inclusion criterion was that potential participants were people with a clinical diagnosis

of schizophrenia who were receiving, or would receive clinical care, on a voluntary basis. Thus, we started with the assumption that accepting voluntary treatment implied that each individual also had capacity to consider the invitation to participate in the COPSI trial, unless there were clear grounds to think otherwise.

As part of the formative research within the early stages of the COPSI trial [17, 18], a small study involving six people with schizophrenia and eight caregivers was conducted in Goa to: (1) understand participant perspectives on who should give consent (the person with schizophrenia or the primary caregiver); (2) explore the capacity of people with schizophrenia to understand and retain the information related to the consent procedure; and (3) to understand the views of persons with schizophrenia and their caregivers about the administration of the consent procedure and suggestions for improvements. These dimensions were explored through in-depth interviews conducted by an independent researcher (who was not involved in the administration of the procedure) and used a short structured interview form 1 h after the main consent procedure. A set of information sheets were developed for this purpose, and trained researchers then conducted the informed consent procedure in a standardised manner. Most people with schizophrenia and their caregivers felt that they could make an independent decision to participate and, if needed, could also have the option of discussing any issues with their caregivers. The recall of the essential sections of the information sheet varied widely between individual participants, suggesting the need for the information to be provided in smaller bits, and to actively discuss and clarify their understanding at the end of each section. Both primary caregivers and people with schizophrenia felt that, while the information provided and the overall procedure were reasonably good, there was considerable room for improvements in making the information sheets simpler and using visual prompts, especially for people who could not read or understand the written material clearly.

Based on this feedback, a number of changes were made to make the consent procedure more interactive, and to make the information materials more easily understandable. These included simplifying the language used in the information sheets, and the development of a flip chart containing simple diagrams to explain the key elements of the study that was to be prominently used in the procedure by the researchers (http://sangath.com/details.php?nav_id=60).

The COPSI consent process and procedure were also influenced by the potential risks involved for people with schizophrenia while participating in the study. Overall, since the risks involved in the experimental arm were not assessed to be substantial, the use of structured tools to assess decisional capacity, such as the 'gold standard' MacCAT-CR [20], was not considered necessary.

Ethical procedures

The final consent procedure (see Fig. 1 below), the information sheets, and consent forms were reviewed and approved by the COPSI Trial Monitoring Committee (TMC), the IRB's of Sangath and SCARF and the Ethics Committees of Kings' College, London and the London School of Hygiene and Tropical Medicine prior to the recruitment of subjects to the main COPSI trial.

The TMC recommended that information collected to monitor the feasibility of the consent procedure was important to capture and could proceed with oral consent from participants and caregivers instead of another set of forms which might be confusing. Finally, a standard operating procedure was developed for this purpose.

The key objectives of monitoring the procedure were to:

- To describe the feasibility of the informed consent procedure from participant, trial and researcher perspectives
- To describe the reasons for participation, or refusal to participate, by people with schizophrenia and their caregivers in the trial.

Methodswere applied to identify significant differences

Settings

COPSI is a multicentre trial involving people with schizophrenia, living with their caregivers in the community, at three sites in India—in rural Tamil Nadu and in two mixed urban and rural sites in Satara and Goa. The key social and service provision characteristics of these sites have been described in more detail elsewhere [18, 19]. Each of the sites had a somewhat different social, economic and cultural profile which presented an opportunity to observe how the procedure worked across diverse settings in India.

Description of the consent procedure

To ensure that the interviewers were similarly skilled across the sites, their training was standardised through the use of a purpose-designed manual (available on request). To maintain fidelity standards across the sites, the consent interview was made as structured as possible. This is described in Table 1 below.

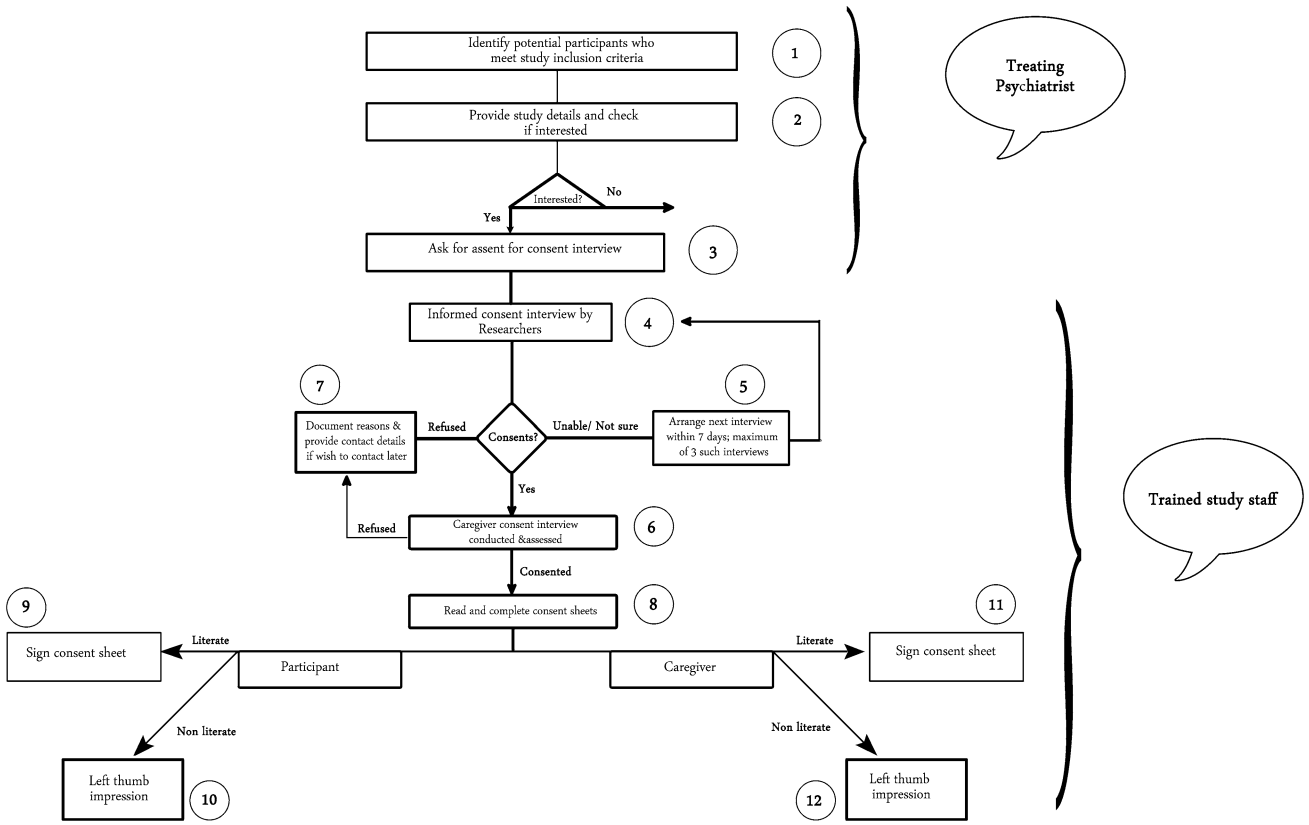

Fig. 1 The COPSI consent procedure flowchart

Table 1 The COPSI consent procedure method

1.	Introduce themselves, remind the participants that they have been sent by their treating psychiatrist and explain the purpose of the interview
2.	Conduct the interview in a respectful and friendly manner
3.	Provide information about each segment of the information sheet using commonly understandable language and encourage clarifications
4.	Use both information materials (information sheets, flip chart) together or as required to cue the participant to the section being discussed and for a multi-modal learning experience
5.	At the end of each segment, check if the participant had understood the key messages in that particular segment and, if necessary, repeat the content of the section in simple terms
6.	Reinforce the participation of the individual in the process to help maintain the motivation and attention span
7.	Fill out the necessary consent documents, as per protocol
8.	Thank the participant before terminating the interview

How did the consent procedure perform?

Three sources of information were used to monitor the performance and gather feedback from key stakeholders involved in the process.

a. Process indicators

Firstly, a set of quantitative process indicators were developed to describe the key steps of the informed consent procedure. These described the number and proportion of people who went through each of the stages of the consent procedure of the main COPSI trial, as well as the reasons for not giving consent. These process indicators allowed for the monitoring of the progress of the consent procedure, in describing the overall feasibility of conducting the procedure, and to highlight any differences between study sites.

b. Consent procedure feedback form

The interviewers conducting the RCT consent procedure completed a specially designed form to record feedback about the consent procedure, from the person with

schizophrenia and key caregiver(s). This form described the operational aspects of the procedure: the setting in which the interview was conducted, whether there was adequate privacy to conduct the interviews, and whether the interview with the person with schizophrenia was conducted alone or in the presence of other people like family member(s) or others. Feedback was also sought from both participants and their caregivers about their perception of the usefulness of the procedure. In addition, both those who agreed to take part in the main COPSI trial and those who refused were asked about their reason(s) for doing so, if they felt the information provided had been adequate or not, and their suggestions for improvements (using simple open-ended questions). Their verbatim responses were written down in the relevant sections of the form. Finally, for a cohort of 191 people and caregivers, more specific details of the comparative utility of the information sheet and the flip chart were collected using a Likert-type scale ('not at all', 'somewhat' and 'a lot').

c. Focus group discussion (FGD) with researchers conducting the consent interviews:

To understand the perspectives of the staff who conducted the consent procedure, a FGD was conducted to explore their experiences with the training, the feasibility and acceptability of the procedure, the challenges they had faced, the solutions they found useful and suggestions for improvement. The interview was conducted by an independent researcher who had no involvement in the consent procedure using an interview guide developed for this purpose; an information sheet describing the rationale for the interview was developed and signed informed consent was taken from all the six participants in the FGD those who participated. The interview was audio taped, transcribed and then analysed by three independent expert researchers.

Data management and analysis

All people with schizophrenia who met the trial inclusion criteria and who were approached by their treating psychiatrists for participation were provided with a unique study identification number to enable them to be followed up through the various steps of the procedure. Study participants and their caregivers were interviewed separately after the informed consent interview, using the semi-structured form during the meeting to seek consent to the main COPSI trial. The pre-specified set of indicators highlighting the key steps of the consent process, as outlined in Fig. 1, were collated on a monthly basis across the sites. The number and proportion of participants at each of the steps were recorded on an Excel sheet after careful checking by the Research Coordinators at the sites. These data (both pooled and for individual sites) were summarised as a flowchart based on the recommended CONSORT guidelines [21].

The supervision and quality control of the data collection process were regulated by a detailed protocol. Onsite supervision (for which the supervisor was present during the interview) was conducted for approximately 10 % of all interviews. After these joint visits, individualised feedback and advice were provided to the interviewer on improving specific aspects of the process. In addition, regular team meetings involving the interviewers and the supervisor were held every week at each site during the recruitment period to discuss difficult situations and doubts. Finally, the supervisors had the opportunity to discuss any issues that had an impact on the overall trial with the trial coordinator and the trial collaborators as a group.

The quantitative data from both sets of the consent assessment forms were entered into SPSS while the qualitative data were entered into a spreadsheet software using Excel. The quality of data entry was checked by comparing a random sample of three original forms from each study site. The files were then screened for missing or inconsistent data. Missing data were excluded per case per analysis.

The categorical data describing the situational details of the setting were analysed by calculating frequencies and proportions for each category. The available socio-demographic measures were analysed to explore any systematic differences between those who consented to participate in the procedure and those who did not at each step. T tests were applied to identify significant differences in the mean age of participants, who decided to participate or not at each of the three stages of the trial. To identify whether educational status played a role in the decision to participate or not in the trial, people with any level of formal education were grouped together and compared with people without any formal education. To determine any significant differences between these groups as well as for the proportions of men and women at each stage, χ^2 tests were conducted.

The qualitative data on reasons for acceptance or refusal were analysed using a thematic content analysis approach. New emerging themes were noted down and later integrated into a coding framework developed in an iterative way.

The data from the FGD were analysed using thematic content analysis. Open coding was used to identify common themes. This was done by two researchers independently using NVivo demonstration version 9 (http://www.qsrinternational.com/products_nvivo.aspx). Both researchers then individually developed a coding framework. The coding frameworks were compared and discussed and a joint coding framework was developed. The coding schemes were largely overlapping, thus the remaining data

were coded by one person on the basis of the coding framework.

Role of funding agency: the sponsors of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the paper. The first author had full access to all the data in the study and had the final responsibility for decision to submit for publication.

Results

Feasibility of conducting the consent procedure

The pooled process indicators illustrating the flow of participants at various stages of the consent procedure and eventual enrolment in the trial are displayed in Fig. 2.

Of the 434 people approached by the treating psychiatrists for participation, 383 (88 %) provided assent to undergo the formal consent procedure. Of those who had assented, the consent procedure could not be conducted for 51 (13 %) of participants. The main reasons were refusal by people with schizophrenia and/or their caregivers after further discussions within the family, and other relatives and logistical reasons such as not getting an appointment time, or inadequate contact details.

A total of 332 consent interviews were carried out across the three sites. Of these, 303 (91 %) of participants and/or caregivers agreed to participate in the trial. Following the provision of informed consent, 21 participants either withdrew their consent, or were later excluded due to logistical problems involved in delivering the intervention. As per protocol, the final number entering the COPSI trail was 282 people with schizophrenia and their primary caregivers [19].

There were no systematic differences between people with schizophrenia who agreed to proceed through the various stages of the consent procedure and those who did not with regard to age and having received formal

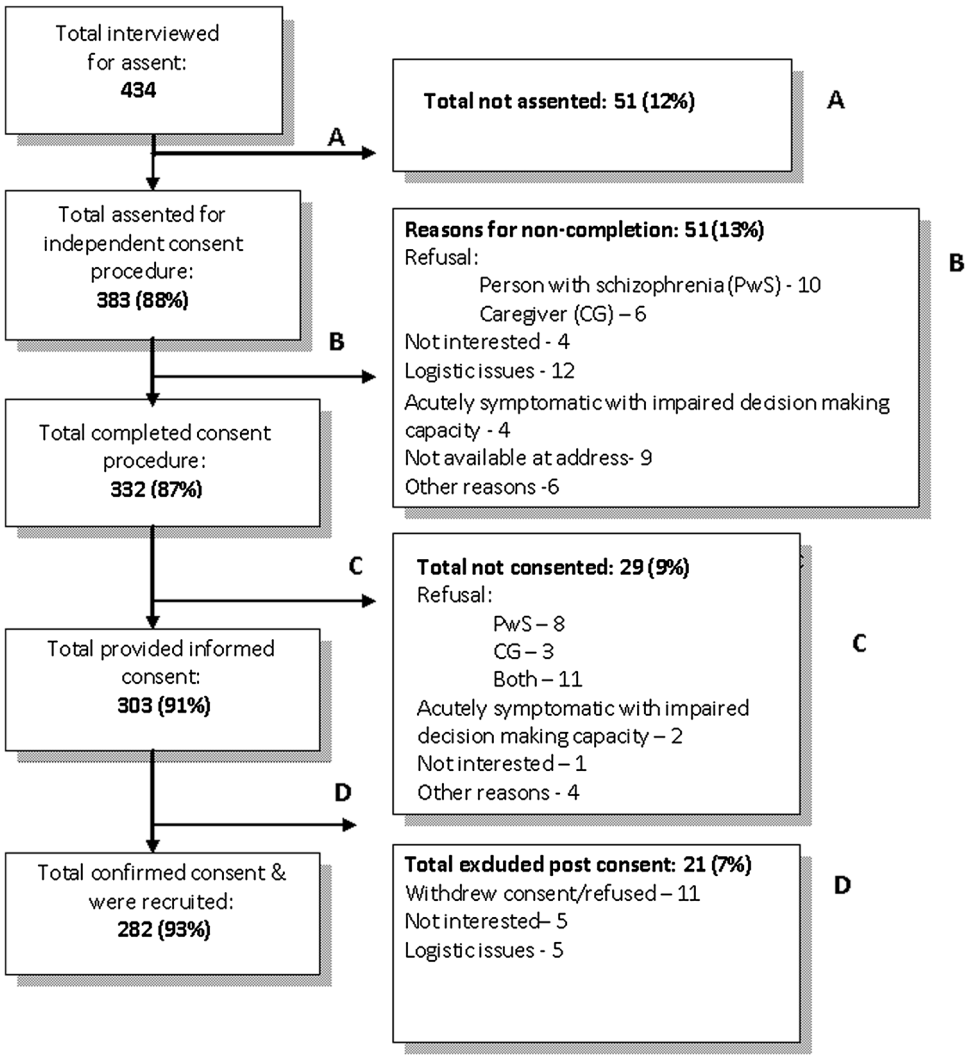

Fig. 2 Flow of participants through the consent procedure stages

Table 2 Socio-demographic differences between people with schizophrenia who consented or refused at various stages of the procedure

Variable	Stage		
	Assent ($N = 434$) Not assented: $n = 51$ (11.7 %)	Completion of procedure ($N = 383$) Not completed: $n = 51$ (13.3 %)	Decision making ($N = 311$) Not consented: $N = 29$ (7.3 %)
Mean age with SD, p value	Assented: 36.4 years (SD 10.36)	Completed: 36.32 years (SD 10.39)	Consented: 36.1 years (SD 10.19)
	Not assented: 41.3 years (SD 11.58)	Not completed: 37.2 years (SD 10.24)	Not consented: 36.1 years (SD 9.95)
	$p = 0.181$	$p = 0.567$	$p = 0.561$
Sex	Male:	Male:	Male:
	assented $n = 190$	completed $n = 165$	consented $n = 149$
	Not assented $n = 14$	Not completed $n = 25$	Not consented $n = 10$
	Female:	Female:	Female:
	assented $n = 193$	completed $n = 167$	consented $n = 133$
	Not assented $n = 37$	Not completed $n = 26$	Not consented $n = 19$
	$p = 0.002$*	$p = 0.524$	$p = 0.045$
Education	Formal education completed:	Formal education completed:	Formal education completed:
	assented $n = 358$	completed $n = 311$	consented $n = 265$
	Not assented $n = 46$	Not completed $n = 47$	Not consented $n = 29$
	Education not completed:	Education not completed:	Education not completed:
	assented $n = 25$	completed $n = 21$	consented $n = 17$
	Not assented $n = 5$	Not completed $n = 4$	Not consented $n = 0$
	$p = 0.269$	$p = 0.759$	$p = 0.181$

education or not. However, both at the stage of seeking assent and in the decision-making stage, a larger proportion of women refused consent, as shown in Table 2. No significant differences between the three sites were noted with respect to this.

Across the sites, 41 % ($n = 137/332$) of the informed consent interviews were conducted in a treatment facility while 59 % ($n = 195/332$) of the interviews were conducted at the homes of participants. The majority of the consent interviews (69 %, $n = 228/332$) involved the person with schizophrenia and a close family member also being present; less often, more than one such person was present during the interview process with the participant. Overall, privacy was perceived as adequate by the majority of participants (65 %, $n = 216/332$).

Participant feedback

When asked, 69 % ($n = 229/332$) of the participants felt that the procedure was very useful, about 30 % (101) felt it was only somewhat useful while two people stated that they were not at all satisfied with the procedure. There were no significant differences between the sites in this regard.

The comparative ratings on the overall and individual domain utility of the information sheet and the flip chart were available for 164 (86 %) of the 191 people with schizophrenia, who were approached to do so, on an ordinal scale described earlier. For almost all of the domains, other than for domains "confidentiality" and "risks and benefits", there was a statistically significant trend for the flip chart to be rated as being more useful by study participants.

Feedback from researchers conducting the procedure

The manual-based training on the process of obtaining consent was greatly appreciated and found very useful, as illustrated by this quote from one of the staff members- "Definitely without the training everything would have gone wrong". The FGD participants also felt that, despite undergoing the initial training, several other unanticipated issues came up when they were out in the field. On such occasions they had to often consult their supervisor and seek advice which was readily available to them. Thus, they felt that training did not end with the initial few structured sessions but was an ongoing process which was found very useful.

> "So the training did not end with the beginning introductory thing; it was on a daily basis so towards the end we became quiet adapted in it"

The duration of the entire COPSI assessment interview process, first with the person with schizophrenia and then with their primary caregiver, was variable and could stretch up to 2 h. Some of the FGD participants felt that it

would be preferable to shorten the procedure, while others were of the opinion that this amount of time was required to be go through the process in detail. The logistical difficulties they encountered included problems related to fixing a mutually convenient time for appointments at homes when the primary caregiver was working and not having enough details to locate homes of participants, especially in rural areas.

Amongst the various components of the informed consent requirements, the participants in the FGD felt that communicating concepts such as "research", "randomization" and "trial" to people with schizophrenia and caregivers were the most problematic to convey and needed investment of considerable time to clarify.

> "So use some object or something like that so they can understand because what happens is the concept is often not clear to them; sometimes I had to take two glasses and tell this is one group of people and this is another group of people to help them understand what is randomization".

In addition, all participants in the FGD felt that, there were a number of other significant people who also played an important role in improving the feasibility of the procedure. For example, they said that it was important for the treating psychiatrist to clearly explain the purpose of the study and to assure the continuation of the regular treatment, irrespective of their choice as this made the procedure far easier to conduct. Caregivers were also seen as playing an important role in facilitating the process through witnessing the procedure and explaining and clarifying difficult concepts to their unwell family member. When both were unable to read, neighbours, nominated by the family, were often consulted to take part in the informed consent procedure to ensure the procedure was witnessed and properly understood.

The training and confidence of the interviewer were highlighted as another reason for the high acceptability of the procedure across the sites in the trial. As one of the consent interviewers said—"I think the overall procedure as such is acceptable but I think a lot depends on how the person who takes the consent approaches the patient—it all depends on how we are implementing it and how we are explaining it to the patient".

Finally, staff conducting the procedure also felt that the flip chart was more effective in communicating the information in a lively and interactive manner and was their preferred choice as it was 'more practical' and 'easier to use'. For the more straightforward concepts, such as "duration of the interview" and "home visit" they too felt both the flip chart and the information sheet were equally useful and that the more abstract concepts such as 'randomization' were better explained by the flip chart.

When asked for suggestions to improve the procedure, the staff in the FGD strongly felt that the flip chart could be improved to further maximise the benefits of visual means of information provision for people with schizophrenia and to make a copy of the flip chart available to participants for their reference in future.

> "I think one thing that is that if the flip chart it could be a little colourful, I think it will help in sustaining their attention. Probably along with the informed consent sheet, providing a copy of the flip chart will be good".

Reasons for choosing to participate or not in the COPSI trial

Across the three settings, the main reason for participants agreeing to be a part of the trial was an expectation of improvement of their own overall situation. Another important reason for wanting to participate was the possible provision of home-based care and having a person come home to talk to them. For caregivers, the major reason for participation in the trial was the expectation of some improvement of the health situation of their ill family member that could reduce their long-term burden of caring. The staff in the FGD group also stressed that, in their experience, participation was also positively influenced by the assurance of confidentiality, continuation of treatment and that that they were free to withdraw at any time of the trial without any negative impact on their ongoing treatment.

The main reason for not agreeing to be a part of the trial was the fear of public disclosure through participation in the trial, leading to negative social experiences for the person and the family in general. This was particularly true in the case of young unmarried women where the family felt repeated home visits by the intervention or research staff would lead to neighbours becoming aware of the illness status of the subject and thus compromising her marriage prospects. Alternatively in situations where neighbours were already aware about the illness the family feared that the frequent visits would be perceived as an increase in the severity of the illness. The staff conducting the interview endorsed this as well and said that in some situations like these, reemphasizing the confidentiality of data and personal information and flexibility of the choice of venue for delivering the intervention such as using neutral venues like a park, etc., was a useful strategy to encourage participants and their caregivers to participate. Another common reason for refusal was the logistical difficulty of caregivers who were very busy at work and could not take time off for family sessions. Some participants also refused to provide any reason for not being interested; a few amongst them cited the information sheet

which stated that there was no requirement to provide a reason for refusing.

Discussion

The COPSI informed consent procedure was developed to address some of the most common challenges faced by people with schizophrenia in providing informed consent for participation in clinical trials in LMIC settings. The adaptations made to address these barriers included: systematic, ongoing capacity building of staff conducting the interviews, the supervision process to meet fidelity and quality assurance standards across the sites, operational modifications to maximise autonomous and informed decision making and the development of information material like the carefully designed information sheet and the flip chart to promote easier understanding of information necessary to make an informed judgment.

From the perspective of trial management, the efforts made in developing the consent procedure carefully and being mindful of local context were well worth the effort. The supporting materials developed for this purpose were also found to be quite useful in communicating key concepts in more easily understandable terms and especially for those who could not read. The attrition rate of 10 %, much lower than the 12 % [22] to 14 % [23] reported from comparable studies from LMIC settings, during the process of conducting the whole of the informed consent procedure is also encouraging suggesting that attention to detail that improves information sharing actually helps informed recruitment.

For the majority of participants and their key caregivers, the procedure was felt to be useful while the flip chart emerged as the preferred method of communicating trial requirements clearly. The researchers conducting the procedure were also reasonably satisfied with the overall experience, even though there were several areas for potential improvement. Thus, overall, there is some preliminary evidence that appropriately designed consent procedures are helpful in getting people with schizophrenia in LMIC settings participate in clinical trials in an informed manner.

The risk of disclosure of the illness, by participating in a trial, emerged as a common concern for not wanting to participate. This was especially a concern for women both at the stage of assent and after completion of the procedure and reflects the disproportionate stigma that females with schizophrenia and their families face in India [24]. Addressing this concern for women to participate in clinical trials in India is a particularly difficult challenge that needs further work. For those who chose to participate, the main reasons for doing so related to expectations of improvement and potential convenience of receiving home-based care.

The fact that the majority of the study participants felt that there was adequate privacy despite the fact that there was a family member present during the process is closely linked to the autonomy in decision making wherein family members frequently make the major decisions regarding the treatment of an ill relative. This is not a situation unique to India and has also been reported from other LMICs such as Pakistan, where the consent form was frequently signed by the family member rather than the patient [25].

The compromise on privacy can also be attributed to the fact that several of the consent interview/procedures were carried out at the homes of the patients and in many instances the houses were modest single room structures with limited privacy available.

A pragmatic balance between desired privacy and participant convenience and power status when the process is carried out at their own homes rather than at a clinic needs to be attained.

These findings are based on observations from a cohort which in their current form have limited internal validity or generalizability. Indeed, the methods employed were not designed to answer these questions in a rigorous manner but to test whether the additional efforts to develop and implement a locally appropriate informed consent procedure were warranted. All that can be concluded is that there is a suggestion that this might be the case. In future studies, it would also be useful to examine the degree to which study participants feel pressured to participate in the study given the highly skewed power differential between doctors and potential research participants in countries like India. Apart from this, the next step should be to refine informed consent procedures and rigorously test their comparative effectiveness. This is both a methodological and ethical obligation for further research involving people with schizophrenia in LMIC settings.

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