

Readiness to Participate in Psychiatric Research

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Background: The feasibility of clinical trials depends, among other factors, on the number of eligible patients, the recruitment process, and the readiness of patients to participate in research. Seeking patients' views about their experience in research projects may allow investigators to develop more effective recruitment and retention strategies.

Methods: A total of 100 patients consecutively admitted to a psychiatric university hospital were interviewed with respect to their willingness to participate in a study. For a different study scenario, patients were asked whether they would be ready to participate if such a study were organized in the service and to indicate their reasons for refusing or for participating.

Results: The general readiness to participate in a study ranged between 70% and 96%. The prospect of remuneration did not notably augment the potential consent rate. The most common and spontaneous motivation for agreeing to take part in a study was to help science progress and to allow future patients to benefit from improved diagnosis and treatment (87%). The presence or lack of a financial incentive was rarely chosen as an argument to agree (23%) or to refuse (7%) to participate. Patients relied mainly on their treating physicians when contemplating possible participation in a study (family physician [65%] and hospital physician [54%]).

Conclusions: Clinicians and, in particular, treating doctors can play an important role in facilitating the recruitment process.

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Clinical Implications

- A significant proportion of hospitalized psychiatric patients would participate in clinical studies.
- Psychiatric patients would participate in clinical studies principally for altruistic reasons.
- Clinicians and, particularly, treating doctors can play an important role in facilitating the recruitment process.

Limitations

- The hypothetical nature of research projects that are described to patients may render them more acceptable to the patients. In a real recruitment situation, the acceptance rate might be significantly lower.
- Because the presented data were from 1 site only, extrapolation to other sites should be done with caution.

Key Words: *informed consent, physician–patient relationship, feasibility study, patient participation, patient selection, decision making*

The feasibility of clinical trials depends, among other factors, on the number of eligible patients, the recruitment process, and the readiness of patients to participate in research. Generally, not more than 5% to 10% of patients who are screened for large, multicentre trials on affective disorders and schizophrenia are recruited (1). Greil and others have shown that a large number of patients may not participate in a trial for reasons other than the formally stated inclusion and exclusion criteria. (2). One of the major obstacles to inclusion may be clinicians' belief that the research is intrusive. They

often may overestimate the negative effects from participating in research, compared with patient perception (3,4).

Although the selection and the recruitment process of patients is of crucial importance for evaluating the generalizability of the results obtained in clinical trials, until now only sparse attention has been directed to these topics (2). Seeking patient views about their experiences in research projects may allow investigators to identify areas of research that are important to patients, to question how patients' experiences may affect

research outcomes, and to develop more effective recruitment and retention strategies.

The objectives of this study were to evaluate the general readiness of psychiatric inpatients to give their consent to different forms of studies and to assess their reasons for accepting or refusing a hypothetical participation.

Methods

The survey took place in the psychiatric hospital of the University of Lausanne, Switzerland, which serves an urban and suburban catchment area of 240 000 inhabitants. Age range of admitted patients was 18 to 65 years. About 1500 admissions are registered yearly, and the mean length of stay is 21 days.

A total of 100 patients consecutively admitted to the hospital were contacted during the first 3 days of hospitalization and were interviewed with respect to their willingness to participate in a study. The following inclusion criteria were chosen to exclude patients who would be ineligible for studies for practical reasons: 1) the ability to give informed consent to a study, 2) sufficient knowledge of at least 1 official Swiss language (French, German, or Italian), and 3) expected hospitalization duration of at least 3 days.

Data were collected with a semistructured interview specifically designed for this study. After patients gave their consent for an interview, study scenarios were described and explained. These included a drug trial with an already marketed medicament, a premarketing drug trial, a double-blind drug trial, a blood sampling (for example, genetic analyses), a study based on 1 interview, repetitive interviews, a study that required interviewing family members (that is, for epidemiologic purposes), and a follow-up after the hospital discharge. For each study scenario, patients were asked whether they would be ready to participate if such a study were to be organized in the service. If the patient refused a study type, it was proposed again, but this time with the additional prospect of a financial indemnity for participants.

Next, we explored the reasons for patient refusal or agreement to participate in studies generally. We asked the patients for their reasons for not participating, even though they had agreed to participate in all types of studies in the first part of the interview. In the same way, we requested that they provide reasons for favouring participation, even though they refused all previous studies. This was first explored with an open question. Subsequently, patients were asked to select reasons or motivations from a list of predetermined answers. The predetermined answers for favouring participation were as follows: 1) the potential benefit from a new treatment, 2) the potential advantage of consideration as a "special" patient, 3) to please the physician, 4) to aid science progress and to help future patients, and 5) the financial incentive. The

predetermined reasons against participation included the fear of being considered a laboratory rat, the fear of adverse drug events, the potential inefficacy of the study treatment, unwillingness to waste time with research, the lack of financial incentives, and the lack of confidence in research doctors.

In a final question, the patients were asked to choose from a list of persons from whom they would seek advice while deciding on participation in a study. The proposed alternatives were a relative, a friend, the family physician, the hospital physician, a nurse, another caregiver, and other patients.

Finally, data were collected concerning the diagnosis (ICD-10), the sex, the age, and the occurrence of previous hospitalization.

The impact of sex, age, previous hospitalizations, and diagnosis on the readiness to participate and on the reasons for agreeing or refusing to participate in a study was assessed using chi-square or Student's *t*-test statistics.

Results

All patients consecutively admitted were screened for eligibility, and the first 100 (59 women and 41 men) who met the criteria were interviewed. Of the patients, 56% had been hospitalized previously at the psychiatric hospital, University of Lausanne. The mean (SD) age was 36.6 (12.7) years. The primary diagnosis was defined as the one that motivated the current hospitalization. The primary diagnosis categories, according to ICD-10, were organic mental disorders (F0) (2%); mental and behavioural disorders owing to use of psychoactive substances (F1) (8%); schizophrenia, schizotypal, and delusional disorders (F2) (30%); mood (affective) disorders (F3) (42%); neurotic disorders (F4) (4%); and disorders of adult personality and behaviour (F6) (14%).

Consent to Participate in Different Hypothetical Studies

Table 1 shows the results of the questions about the consent for different hypothetical studies. The general readiness to participate was rather high in our sample, with rates ranging between 70% and 96%. The perspective of remuneration did not notably augment the potential consent rate. The highest potential consent rate was observed in studies that consisted of interviews and that included active participation in drug trials. Likewise, a high consent rate was observed in studies that involved family members or in instances for which the required follow-up beyond hospitalization was lower, but with rates above 70%.

Reason for Agreeing or Refusing to Participate

Table 2 shows that the most common motivation for participating in a potential study was the intention to help science progress and to enable future patients to benefit from improved diagnosis and treatment (87%), followed by

Table 1 Consent for different hypothetical studies

Proposed hypothetical study	No consent		Consent			
	n	%	Without financial incentive		With financial incentive	
			n	%	n	%
Drug trial	19	19.6	75	77.3	3	3.1
Premarketing drug trial	26	26.8	68	70.1	3	3.1
Double-blind drug trial	25	25.8	71	73.2	1	1.0
Blood sampling	11	11.3	86	88.7	0	0.0
One interview	3	3.1	94	96.9	0	0.0
Repetitive interviews	9	9.4	86	89.6	1	1.0
Interview of family members	27	27.8	69	71.1	1	1.0
Follow-up beyond hospitalization	16	16.7	69	81.3	2	2.1

Table 2 Patients' reasons for favouring and for refusing study participation

	Not a reason		Reason				Total	
	n	%	Spontaneous answer		After suggestion		n	%
			n	%	n	%		
Reasons for favouring study participation								
Possible benefit from a new treatment	34	35.1	20	20.6	43	44.3	63	64.9
Possible advantages as a "special" patient	97	64.9	11	11.3	23	23.7	34	35.1
To please the physician	91	93.8	0	0.0	6	6.2	6	6.2
To help science progress and help future patients	13	13.4	57	58.8	27	27.8	84	86.6
Financial incentive	75	77.3	3	3.1	19	19.6	22	22.7
Reasons against study participation								
Fear of being considered a laboratory rat	49	50.5	19	19.6	29	29.9	48	49.5
Fear of side effects	50	51.5	12	12.4	35	36.1	47	48.5
Fear of receiving ineffective treatment	64	66.0	9	9.3	24	24.7	33	34.0
Reluctance to invest time	64	66.0	15	15.5	18	18.6	33	34.0
Lack of financial incentive	90	92.8	2	2.1	5	5.2	7	7.2
Lack of confidence in physician	82	84.5	1	1.0	14	14.4	15	15.5

possible benefit from a new treatment (65%). With respect to reasons against participation, the most commonly given answers (50% and 49%, respectively) included the fear of being considered a guinea pig and the fear of side effects.

When explored with an open question, most patients revealed that helping science to progress and allowing future patients to benefit from this progress were their main motivations (59%). Of the patients, 20% did not see any reason for not participating in studies.

When patients were presented with a list of possible reasons for agreeing or refusing to participate, there was an increase in the degree of awareness of potential benefits and in the negative consequences of participation. Of the subjects, 44% more indicated that their reason for participating was to possibly benefit

from a new treatment, and 30% mentioned fear of potential side effects as a reason not to participate.

Persons Consulted Prior to Decision

Table 3 illustrates that patients rely mainly on their treating physicians when contemplating possible participation in a study: family physician (65%), hospital physician (54%), followed by relatives (43%).

Impact of Sex, Age, Previous Hospitalizations, and Diagnosis

We describe the significant associations only. Sex had an impact on the type of motivation that patients had to refuse or agree to participation. Women mentioned more often than did men the desire to help science progress and to allow future patients to benefit from new treatments (70.7% vs 41.0%; $P < 0.05$). Similarly, there were significantly more

Table 3 The person with whom patients would discuss possible participation in a study (n = 97)

	n	%
Relative	42	43.3
Friends	17	17.5
Family physician	63	64.9
Hospital physician	52	53.6
Nurse	18	18.6
Another caregiver	7	7.2
Other patients	8	8.2

men than women who saw no reason to refuse participation (20.5% vs 8.6%), as well as more men who mentioned the lack of financial compensation as their reason for not participating (12.8% vs 3.4%; $P < 0.05$). Patients with F2 diagnosis were generally more reluctant to participate in studies. They more often refused postmarketing drug trials (35.7% vs 13.0%; $P < 0.05$), double-blind trials (42.9% vs 18.8%; $P < 0.05$), blood sampling (21.4% vs 7.2%), and repeated interviews (21.4% vs 4.4%). They were less convinced that they would benefit from a newer treatment (50% vs 71%; $P < 0.05$) and indicated less often “to help science and other patients” as their reason for participation (67.9% vs 94.2%; $P < 0.01$). Likewise, they relied less frequently on their family physician to discuss participation (50% vs 71%; $P < 0.05$).

No relation existed between age or previous hospitalization and readiness to participate in a study.

Discussion

It is often difficult to recruit subjects for research projects. The restrictive nature of the inclusion and the exclusion criteria often makes it necessary to assess a large number of patients before a sufficient number of suitable subjects can be identified. Thus, substantial resources need to be allocated to this task (2). Because research is vital for improving care, it is important to identify factors that may complicate the recruitment process. To protect patients from the inconvenience that research projects can create, clinicians as well as researchers sometimes hesitate to propose these research projects. Our results, however, suggest that this assumption may be wrong.

This study's most striking finding is that most patients who were interviewed appeared to have a rather positive view of research; in fact, over two-thirds declared that they would participate in research projects. These results contrast with a recent study of 289 internal medicine outpatients; the overall hypothetical acceptance rate for an intervention trial was much lower (19.7%) (5). It is likely that the hypothetical nature of the research projects described to these patients rendered them more acceptable and that, in a real recruitment situation, the acceptance rate might be significantly lower. This

is suggested by the observation that the schizophrenia patients (who sometimes seemed to think their answers would commit them to research) had a lower acceptance rate. Further, the results may have been influenced by a social desirability bias, patients being keen to please their doctors, and even more so, if no real risk existed from inclusion in a study.

Nevertheless, the most common spontaneously mentioned motivation for agreeing to take part in a study was the intention to help science progress and to allow future patients to benefit from improved diagnosis and treatment. This altruistic motivation gives more credibility to the high potential acceptance level that is observed and is in keeping with the previous observation that patients with schizophrenia view helping others and helping science as important reasons for protocol participation (4). Weiss Roberts and others observed that patients endorse the feeling of hope associated with research involvement, a perspective that was underestimated by the psychiatrists interviewed during the same study (4). Similarly, in a further study, psychiatric patients noted that participating in the research allowed them to contribute to the care of other patients and to donate to science (6).

Another interesting observation is that, although money is often considered a motivator that could positively influence patient willingness to participate in a study, the impact of monetary incentives was marginal in our study, convincing few formerly reluctant patients to consent. Likewise, the presence or lack of a financial incentive was rarely chosen as an argument to agree or refuse to participate. This confirms other studies, wherein results have found that a clinician's recommendation to support participation was a positive influence and had similar value to a monetary incentive (6,7). Although 43% of patients indicated that they would discuss their possible participation with relatives, more patients stated that they would rather rely on their treating physicians, either their family doctor (65%) or their hospital physician (54%). This confirms previous findings that patients greatly value the advice of their doctors with respect to research—an impact that psychiatrists tend to underestimate (4,7).

Still, this study has some important limitations. Patients may have a different attitude toward the prospect of real enrollment in a research project, and the validity of the procedure may be questioned: direct comparisons of consent to real and hypothetical studies have until now remained unpublished. It is likely, however, that the patients were able to perceive the implications of the various types of projects that were proposed and that their readiness to participate was determined by this perception. Previous studies have used comparable designs that presented hypothetical studies to patients (5,7–10). These studies suggest that patients were competent to discern study characteristics, such as risks and benefits of specific procedures, when confronted with hypothetical

vignettes in structured interviews and that their assessments of the implications of the studies were similar to those of psychiatrists (7).

In conclusion, although the situation may differ in the context of a real research project, it is likely that an important proportion of hospitalized psychiatric patients would be ready to participate in clinical studies, principally for altruistic reasons. It appears that clinicians, and treating doctors in particular, can play an important role in facilitating the recruitment process. Most patients trust them when they feel ambivalent about participation and would rely on their decision. Clinical research is fundamental for improving treatment. The larger the population studied and the wider the range of patients included, the more likely it is to lead to findings that are applicable and relevant to most patients. Although it is fundamental to allow patients to make an autonomous decision about their participation in a research project, it is also important not to decide for them by assuming that they would, or should, refuse to take part.

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Résumé : La disposition à participer à la recherche psychiatrique

Contexte : La faisabilité des essais cliniques dépend, entre autres, du nombre de patients admissibles, du processus de recrutement, et de la disposition des patients à participer à la recherche. Solliciter les opinions des patients à propos de leur expérience des projets de recherche peut permettre aux enquêteurs d'élaborer des stratégies plus efficaces de recrutement et de maintien en place.

Méthodes : Un total de 100 patients hospitalisés consécutivement dans un hôpital psychiatrique universitaire ont été interviewés au sujet de leur disposition à participer à une étude. Pour un scénario d'étude différent, on a demandé aux patients s'ils seraient prêts à participer si une telle étude avait lieu dans le service, et d'indiquer leurs raisons de refuser ou d'accepter de participer.

Résultats : La disposition générale à participer à une étude variait entre 70 % et 96 %. La perspective d'une rémunération n'augmentait pas notablement le taux de consentement potentiel. Le motif le plus fréquent et le plus spontané d'accepter de prendre part à une étude était de contribuer au progrès de la science et de permettre aux futurs patients de profiter de meilleurs diagnostics et traitements (87 %). La présence ou l'absence d'un incitatif financier était rarement choisie comme argument pour accepter (23 %) ou refuser (7 %) de participer. Les patients se fiaient principalement à leur médecin traitant quand ils envisageaient une participation possible à une étude (médecin de famille [65 %] et médecin hospitalier [54 %]).

Conclusions : Les cliniciens et en particulier, les médecins traitants peuvent jouer un rôle important dans la facilitation du processus de recrutement.