# Patient Satisfaction with Random Assignment to Extended Early Intervention for Psychosis versus Regular Care: Relationship with Service Engagement

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## Abstract

### *Aim*

We investigated whether individuals varied in their satisfaction with being randomized to an extension of early intervention (EI) for psychosis or regular care after two years of EI, and whether satisfaction was associated with service engagement three years later.

### *Methods*

Following randomization, patients (N=220) indicated if they were happy with, unhappy or indifferent to their group assignment. Follow-up with service providers was recorded monthly.

### *Results*

Patients randomized to extended EI were more likely to express satisfaction with their group assignment than those in the regular care group (88.2% vs 31.5%, $\chi^2=49.96$, $p<0.001$). In the extended EI group, those happy with their assigned group were likelier to continue seeing their case manager for the entire five-year period than those who were unhappy/indifferent ($\chi^2 = 5.61$, $p = 0.030$).

### *Conclusions*

Perceptions about EI, indicated by satisfaction with being assigned to extended EI, may have lasting effects on service engagement.

**Keywords:**

Early intervention services, Engagement, First-episode psychosis, Randomization, Satisfaction

## Introduction

Individuals who participate in randomized controlled trials (RCT) of differing service delivery models are rarely asked about their satisfaction with their group assignment. Given the known impact of expectations about treatment on the development of alliance and outcomes in mental healthcare (McClintock, Anderson, & Petrarca, 2015), satisfaction with group assignment may be important to examine for its influence on the likelihood of completing treatment in an RCT of mental health interventions/service models.

We conducted secondary analysis of an RCT where patients were randomized after two years of early intervention (EI) for psychosis to receive extended EI or regular care for three subsequent years. Extended EI included follow-up with the same psychiatrist and case manager at the same EI service, and regular care comprised either primary care or hospital-based outpatient psychiatric services, depending on patients' needs and preferences which were assessed prior to randomization.

After being informed about their randomization to extended EI or regular care, patients were asked whether they were happy with, not happy with or indifferent to the results. Here, we examine whether satisfaction with assigned group varied between the experimental and control groups, and whether satisfaction responses were associated with patients' completion of (or disengagement from) the three-year post-randomization course of treatment.

Given that EI focuses on building strong alliances, we expected that more individuals assigned to extended EI would be satisfied with the results of the randomization. Because satisfaction with the assigned group may be an indicator of expectations about treatment, we predicted that those who were happy with their assigned group would be likelier to complete treatment. We expected satisfaction with group assignment to have a stronger impact on service engagement in the extended EI group where satisfaction served as a proxy measure of patients' alliance with their treating teams.

## Methods

### *Design and sample*

The study was conducted at the Prevention and Early Intervention Program for Psychosis (PEPP) and two other EI services in the McGill University network in Canada which provide equivalent specialized two-year follow-up with psychosocial and pharmacological interventions (Iyer, Jordan, MacDonald, Joober, & Malla, 2015). Patients admitted were 14-35 years old; had a non-affective or affective psychotic disorder previously treated for less than a month and an IQ above 70. Two hundred and twenty patients participated in the RCT where they either received an extension of the two-year (+/-3 months) follow-up (n=110) or were transferred to regular care (n=110) for the subsequent three years. The study protocol and details of care have been previously reported (Lutgens et al., 2015; Malla et al., 2017).

### *Assessments*

On a purpose-built one-item satisfaction questionnaire administered after results of the randomization had been communicated to them, patients were asked to choose one of the following options: “I am happy with the results”, “I am not happy with the results” or “It does not matter to me where I receive services”. Answers served as a measure of satisfaction with assigned group, the independent variable in this study.

The main outcome measure was service engagement status at the end of the trial (three years post-randomization and five years after entry into an EI service), defined as “engaged” (had at least some contact with treatment provider during the last three months) or “disengaged” (had no contact with treatment providers for three or more months before Month 60). Service engagement status was estimated separately for the treating physician and for another healthcare professional (e.g., case manager). Individuals who had missed appointments for three or more months during the three-year follow-up but had returned to services were considered “engaged”.

Demographic characteristics included age of onset, gender, marital status and education. Clinical characteristics included duration of untreated psychosis (DUP) measured by the Circumstances of Onset and Relapse Schedule (Norman, Malla, Verdi, Hassall, & Fazekas, 2004), and positive and negative symptoms at randomization measured by the Scale for the Assessment of Positive Symptoms and the Scale for the Assessment of Negative Symptoms, respectively (Andreasen, 1984a, 1984b).

*Analysis*:

Given the relatively low numbers endorsing being unhappy or indifferent, particularly in the extended EI group, we combined respondents who were unhappy and indifferent into one group. We also did this because our main questions were about who was more likely to be satisfied (“happy”) with their assigned group, and whether satisfaction with assigned group contributed to treatment completion.

ANOVAs for continuous variables and chi-square analyses for categorical variables were conducted to analyse whether groups endorsing different levels of satisfaction (happy versus indifferent/unhappy) with their assigned treatment condition differed with respect to demographics and clinical characteristics, and whether this was moderated by treatment condition (extended EI versus regular care). Group (happy versus indifferent/unhappy); condition (extended EI versus regular care) and an interaction term (group x condition) were entered into these analyses.

To address the main aim, differences between groups endorsing different levels of satisfaction with their assigned treatment condition (happy versus indifferent/unhappy) on service engagement status with treating physician and service engagement status with another healthcare professional were analyzed using chi-square ($\chi^2$) tests.

All analyses were conducted using SPSS version 23. All tests were 2-tailed and *p* values of $\leq 0.05$ were considered significant. Phi (Φ) coefficient was used to calculate effect sizes, with 0.1-0.29, 0.3-0.49 and 0.5+ considered small, medium and large effect sizes, respectively, as per convention.

## Results

There were no significant demographic (age of onset, gender, marital status and education) or clinical (positive and negative symptoms and DUP) differences between individuals who were happy with, or not happy with/indifferent to their group assignment. None of the interaction terms were significant suggesting that the happy versus unhappy/indifferent groups did not differ on these characteristics whether they had been randomized to the extended EI or regular care groups. Supplementary Table _ provides the results of these analyses.

Among those who had been randomized to continue in EI, the majority (88.2%) reported being happy with the results while a minority (11.8%) indicated that they were either not happy or indifferent to where they received services. A third (31.5%) of those randomized to regular care were happy with the results and two-thirds (68.5%) were unhappy or indifferent, with both options (i.e. unhappy or indifferent) being nearly equally endorsed. As hypothesized, those who had been assigned to continue receiving EI were significantly likelier to report being happy than those who had been assigned to regular care ($\chi^2 = 49.96$, $\Phi = 0.58$, $p < 0.001$), indicating that many may have agreed to participate in the RCT hoping for an assignment to extended EI.

Compared to individuals who were unhappy with or indifferent to their group assignment, those who were happy were more likely to continue their follow-up for the entire 60-month period with their physician (53.8% vs. 29.8%; $\chi^2 = 6.87$, $\Phi = 0.23$, $p = 0.009$) and their non-physician healthcare professional (62.5% vs. 23.4%, $\chi^2 = 18.13$, $\Phi = 0.38$, $p < 0.001$). Separately analysing EI and regular care groups revealed that satisfaction was not associated with completing follow-up in the regular care group. In the EI group, however, individuals who reported being happy with their assignment were more likely to continue seeing their case manager for the entire five-year period than those who reported being unhappy or indifferent to continuing in EI (72.6% vs. 28.6%; $\chi^2 = 5.61$, $\Phi = 0.29$, $p = 0.030$). Moreover, compared to those happy with being assigned to regular care, a higher proportion of participants who were happy with being assigned to extended EI completed 60-months follow-up with both their physician (59.7% vs. 33.3%; $\chi^2 = 3.89$, $\Phi = 0.22$, $p = 0.048$); and non-physician (72.6% vs. 27.8%; $\chi^2 = 11.95$, $\Phi = 0.39$, $p = 0.001$) service providers.

## Discussion

The degree of individuals' satisfaction with being randomly assigned to extended EI after an initial two years of EI predicted their ongoing contact with their case manager at the end of the five-year follow-up. Perceptions about EI services, for which satisfaction with being assigned to the extended EI group may serve as a proxy, may be formed early on and have lasting effects on service engagement, an important outcome in psychosis. Our results are also aligned with a recent meta-analysis which found that delivering patient-preferred psychosocial interventions was associated with lower dropout rates and stronger therapeutic alliance (Windle et al., 2020) .

Individuals who were satisfied with being assigned to extended EI may have had a stronger working alliance with their treating team and been more engaged with services during the first two years. Their sustained engagement in care during the subsequent three years may simply be a manifestation of continued alliance. Unfortunately, we do not have pre-randomization working alliance data to test this hypothesis. Further, pre-randomization service engagement data was limited to whether individuals dropped out before the two-year mark and did not capture finer nuances of engagement that may have been more predictive of satisfaction and sustained engagement with assigned group.

Even among those who were satisfied with being assigned to regular care, this was less likely to translate into being in contact with their treatment team at Month 60 compared to those who were satisfied with being assigned to extended EI. Thus, being satisfied with the assigned group may have captured different experiences in the two groups. In the extended EI group, it may have been an indicator of midway satisfaction with treatment, and therefore linked to better outcomes. In the regular care group, it may have been an indicator of positive expectations about treatment. Completing regular care may have been better predicted by actual experiences and alliance with treatment providers in regular care, rather than these expectations. Understandably then, how individuals felt about regular care immediately after randomization also did not impact their likelihood of completing their treatment in regular care.

While our study is limited by the lack of a validated measure of participant satisfaction, it is novel. No other RCT examining the benefits of extending EI (Chang et al., 2015; Melau et al., 2011) has assessed patient satisfaction with group assignment, although individuals in the extended EI arm reported higher levels of satisfaction with services compared to those in the regular care arm in the OPUS-II study (Albert et al., 2017). Overall, few studies assess participant satisfaction with randomization results.

In a trial of aerobic exercise training compared to usual care among cancer survivors, Courneya et al. assessed satisfaction with participating in the trial and with the assigned group. Like our study, theirs used custom-built measures of satisfaction. It assessed satisfaction with trial participation by asking, “With hindsight, how do you feel about participating in the HELP Trial?” in terms of it being rewarding; a waste of time; useful for research; useful for me personally; and something I would recommend to others. Each item was rated on a 7-point scale from “not at all” to “very much”. As in our study, Courneya et al. used a single item to assess satisfaction with assigned group. This item was rated on a 7-point scale from “extremely disappointed” to “extremely pleased”. Courneya et al. found that those who had been assigned to the experimental group (aerobic exercise training) were more satisfied with participating in the trial and the group that they had been randomized to than those assigned to usual care (Courneya et al., 2013). Our results and those of Courneya et al. could be partially attributed to individuals tending to assume the superiority of one of the two arms of an RCT.

One noteworthy limitation is that our service engagement measure was crude. Our “disengaged” group including individuals who lost contact with their provider at varying time points between Months 24 and 60. Further, the “non-physician healthcare professional” was always a case manager in the extended EI arm but could have been another professional (e.g., nurse administering injections) in the regular care arm.

*Implications:*

Measuring participants’ satisfaction with the treatment conditions being compared in an RCT may be useful to assess the clinical equipoise of a trial from the patient perspective. In this regard, both our study and that of Courneya et al. (2013) provide inspiration.

The risk of dropping out of early psychosis treatment in the first two years is about 20-40% (Doyle et al., 2014). Our findings suggest that this risk persists throughout the five-year critical period, even in an arguably already better engaged patient cohort that stayed to complete the first two years of treatment and agreed to participate in a trial. Further research is needed to elucidate why individuals with psychosis engage/disengage from services and how this evolves over time. Such work can help maintain service engagement, which may in turn help sustain (or engender) clinical and functional gains later in the course of treatment.

Overall, irrespective of where individuals are receiving services, there may be much clinical value to regularly assessing patient satisfaction. This may not be happening in part because there are no satisfaction measures specifically tailored for use in EI for psychosis settings. The two multi-item measures that have been used in early psychosis are the Client Satisfaction Questionnaire (Attkisson & Zwick, 1982; Marino et al., 2015; Verma, Poon, Subramaniam, Abdin, & Chong, 2012) and the Verona Service Satisfaction Scale (Garety et al., 2006; Nash et al., 2004). Future services research should explore the potential of simple one-item measures such as the one in this study as they may be more readily implementable in clinical settings.

## Conflict of interest

In the past three years, Dr Malla reports honoraria for lectures delivered on early intervention at conferences sponsored by Otsuka and Lundbeck (Canada and Global); and consulting activities related to research with Otsuka and Lundbeck, Canada. Dr. Joober reports to be a speaker and/or consulting committee member for Pfizer, Janssen, BMS, Sunovian, Myelin, Otsuka, Lundbeck, Shire and Perdue, and to have received grants from Janssen, BMS, Otsuka, Lundbeck, Astra Zeneca and HLS, and to have royalties from Henry Stewart talks. Dr. Margolese reports to be a paid speaker and/or consulting committee member and/or to have received honoraria from: HLS Therapeutics, Janssen, Lundbeck, Mylan, Otsuka, Pfizer, Shire, Sunovion; Research Support: Acadia, Amgen, Lundbeck, Janssen, and SyneuRx.

All mentioned conflicts of interest are unrelated to the present article.

Authors Iyer, Mustafa, Abadi, Abdel-Baki, Brown, Casacalenda, Jarvis, Latimer and Schmitz have no conflicts of interest.

## Acknowledgement:

This study was supported by an operational grant from the Canadian Institutes of Health Research (grant MCT 94189; registration CCT-NAPN-18590). The authors thank Nicole Pawliuk for assistance with data and all study participants and their families.

## Data availability statement:

Data available on request due to privacy/ethical restrictions.

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**Supplementary table. Demographic and clinical comparison between assigned treatment conditions (extended early intervention vs regular care), satisfaction levels with the assigned group (happy vs. unhappy or indifferent) and their interaction**

| **Variable** | **Type of care** | | | | **Satisfaction with group assignment** | | | | **Interaction (care X satisfaction)** | |
|---|---|---|---|---|---|---|---|---|---|---|
| | **Regular care** | **Extended EI** | | | **Happy** | **Unhappy/ indifferent** | | | | |
| | **N (%)** | **N (%)** | **$X^2$** | **p** | **N (%)** | **N (%)** | **$X^2$** | **p** | **$X^2$** | **p** |
| **Male** | 76 (69.1%) | 75 (68.2%) | 0.02 | 0.88 | 65 (72.2%) | 43 (72.9%) | 0.01 | 0.930 | 3.49 | 0.062 |
| **Single** | 97 (88.2%) | 103 (93.6%) | 1.98 | 0.16 | 83 (92.2%) | 55 (93.2%) | 0.05 | 1.00 | 0.00 | 0.999 |
| **Completed high school** | 73 (67.6%) | 76 (69.1%) | 0.06 | 0.81 | 58 (65.2%) | 45 (77.6%) | 2.58 | 0.11 | 0.34 | 0.559 |
| | **Mean (SD)** | **Mean (SD)** | **F** | **p** | **Mean (SD)** | **Mean (SD)** | **F** | **p** | **F** | **p** |
| **Age of FEP onset** | 22.90 (4.66) | 21.87 (4.12) | 1.23 | 0.269 | 22.00 (4.26) | 23.26 (4.42) | 0.43 | 0.512 | 0.05 | 0.819 |
| **Log DUP** | 1.20 (0.65) | 1.08 (0.70) | 3.29 | 0.072 | 1.09 (0.73) | 1.02 (0.58) | 2.57 | 0.111 | 0.17 | 0.685 |

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **SAPS at randomization** | 6.00 (8.95) | 7.07 (10.39) | 0.24 | 0.624 | 6.54 (8.19) | 5.05 (6.76) | 0.36 | 0.551 | 0.00 | 0.983 |
| **SANS at randomization** | 14.03 (12.79) | 13.58 (10.43) | 0.02 | 0.884 | 14.29 (11.19) | 14.20 (13.09) | 0.05 | 0.830 | 0.91 | 0.342 |

EI = Early intervention; SD = Standard deviation; FEP = first-episode psychosis; DUP = duration of untreated psychosis; SAPS = Scale for the Assessment of Positive Symptoms; total score minus global items ranges from 0 to 150; SANS = Scale for the Assessment of Negative Symptoms; total score ranges from 0 to 90 after removal of global items and items for attention.