



Recruiting and Retaining Individuals with Serious Mental Illness and Diabetes in Clinical Research: Lessons Learned from a Randomized, Controlled Trial.

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### Abstract

Abstract: Recruitment and retention of individuals with serious mental illness (SMI) and comorbid diabetes mellitus (DM) in research studies can be challenging with major impediments being difficulties reaching participants via telephone contact, logistic difficulties due to lack of transportation, ongoing psychiatric symptoms, and significant medical complications. Research staff directly involved in recruitment and retention processes of this study reviewed their experiences. The largest barriers at the macro, mediator, and micro levels identified in this study were inclement weather, transportation difficulties, and intermittent and inaccessible telephone contact. Barrier work-around practices included using the health system's EHR to obtain current phone numbers, providing transportation assistance (bus passes or parking reimbursement), and flexible scheduling of appointments. Suggestions are intended to assist in planning for recruitment and retention strategies.

### Keywords

Mental illness; schizophrenia; bipolar disorder; depression; diabetes mellitus; recruitment; study retention

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**ABSTRACT**

Recruitment and retention of individuals with serious mental illness (SMI) and comorbid diabetes mellitus (DM) in research studies can be challenging with major impediments being difficulties reaching participants via telephone contact, logistic difficulties due to lack of transportation, ongoing psychiatric symptoms, and significant medical complications. Research staff directly involved in recruitment and retention processes of this study reviewed their experiences. The largest barriers at the macro, mediator, and micro levels identified in this study were inclement weather, transportation difficulties, and intermittent and inaccessible telephone contact. Barrier work-around practices included using the health system's EHR to obtain current phone numbers, providing transportation assistance (bus passes or parking reimbursement), and flexible scheduling of appointments. Suggestions are intended to assist in planning for recruitment and retention strategies.

**Keywords:** Recruitment, retention, serious mental illness, diabetes

**INTRODUCTION**

Landmark diabetes mellitus (DM) treatment studies such as the Diabetes Prevention Program have specifically excluded people with serious mental illnesses (SMI) such as

schizophrenia, bipolar disorder and severe or recurrent major depression (The Diabetes Prevention Program Research Group, 2000). This is unfortunate since people with SMI are a sub-group that are particularly likely to develop DM, have more complications once they have DM, and are likely to die earlier from DM compared to individuals in the general population (Dembling, Chad, & Vachon 1999; Miller, Paschall, and Svendsen 2006). Factors that increase the likelihood that people with SMI will develop DM and will do poorly in living with DM include side effects of psychotropic drugs, especially second-generation antipsychotics, and widely prevalent unhealthy behaviors, such as reduced physical activity and poor diet (Daumit 2005, Dipasquale 2013, Jerome 2009). Fortunately there is a growing body of research that specifically focuses on improving physical health and DM in people with SMI (Bartels 2014, McKibbin 2006, Daumit 2013). There is not extant literature on recruiting and retaining individuals with SMI and DM to research studies, and this article provides pragmatic recommendations.

Recruiting and retaining individuals with SMI in clinical trials, especially for extended periods of time can be extremely challenging (Loue and Sajatovic 2008). This article is intended to assist future researchers to recognize and address potential barriers to recruitment and retention; to plan for these activities during study development. The inherent pathology in chronic psychotic conditions and serious mood disorders such as paranoia, social isolation and lack of motivation make it difficult to get research participants to adhere to sometimes complicated research study procedures and protocols. In longitudinal studies involving people with SMI, rates of attrition in the order 25-60% have been reported (Sobell 1987, Morrissey 1990). Additionally minorities are over-represented among people with SMI, and this adds to research recruitment challenges. Individuals from minority groups are less likely to participate in research compared to non-Hispanic whites (Murry 2003). Factors that may reduce the ability and/or willingness of ethnic minorities to participate in health research include limited economic resources, past negative experiences with health professionals, and a socioeconomic or ethnic status that differs from that of the researcher (Atwood 1992).

We use a model outlined by Levkoff and Sanchez (2003), which frames barriers to involvement in research for minority populations in the context of macro, mediator, and micro (individual) level barriers and enablers. Building upon the Levkoff and Sanchez model, Loue and Sajatovic (2008) report on recruitment and retention of minorities with SMI in clinical research that focuses on barriers and enablers to recruitment. Macro-level barriers are those that exist in the environment or culture generally, mediator-level barriers are those that impact how individuals connect to health services, and micro-level barriers are factors specific to the individual. The presence of DM, a chronic and often disabling medical comorbidity makes it even more difficult for people with SMI to participate in research studies. This article uses the model outlined by Levkoff and Sanchez to describe challenges and solutions to address personal (micro), community (mediator), and environmental/systems (macro) level barriers to research recruitment and retention of multi-morbid individuals with SMI and DM participating in a randomized controlled trial (RCT). Implications for future research as well as clinical practice are also discussed.

## **METHODS**

### **RCT Description**

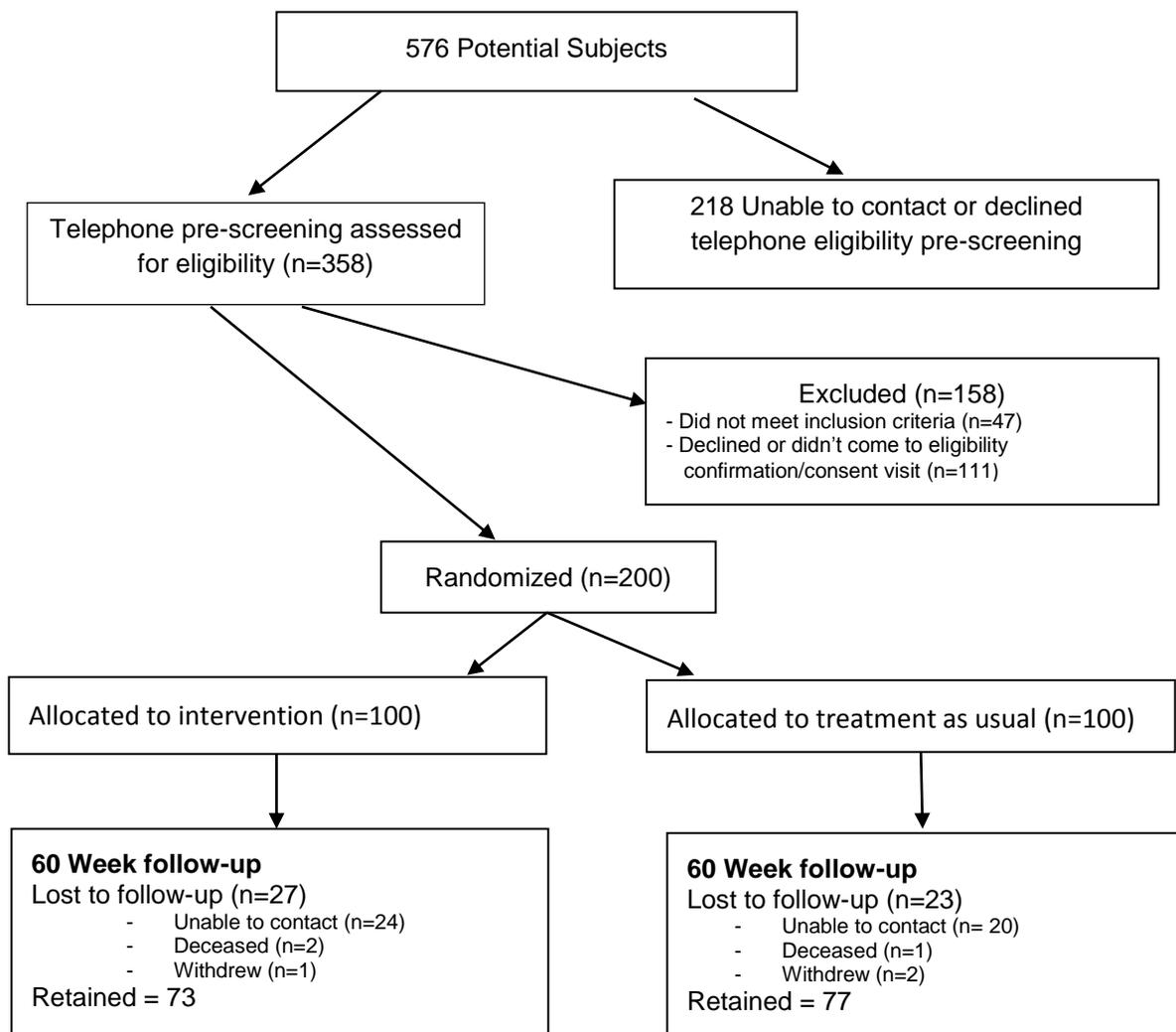
This prospective RCT testing a novel behavioral intervention to improve outcomes in SMI-DM recruited 200 individuals age 18 to 89 conducted in a safety-net health system primary care setting. Inclusion criteria included having a diagnosis of schizophrenia, schizoaffective disorder, bipolar disorder or major depression and DM, being able to communicate in English; and able to provide written, informed consent to participation. Exclusion criteria included being actively suicidal/homicidal, being unable to be rated on study rating scales, having dementia, being pregnant; being unable to participate in groups, or having special physical and/or dietary needs not consistent with the experimental intervention.

Subjects were randomized to either the Targeted Training in Illness Management (TTIM) intervention or to treatment as usual (TAU) and followed for a period of 60 weeks. The TTIM intervention consisted of a series of 12 weekly group-format psychoeducation sessions (6-10 participants per group) followed by phone calls every 2-4 weeks for a 48 week period. Individuals in TAU did not receive services beyond their usual clinical care. Research assessments were conducted at study screening, baseline and at weeks 13, 30 and 60 week follow-up for subjects of TTIM and TAU. Subjects were compensated \$25.00 for each of these assessments.

### **RCT sample**

Figure 1 illustrates screening, enrollment and study flow procedures conducted from 11/22/11- 6/3 0/15. Enrolled participants were 64% female and 36% male, 53% African American, 37% Caucasian, and 10% Hispanic. Age ranged from 25 to 73 years (mean = 54; SD = 9.4). Mean level of education was 13 years (SD = 2.7). On average, individuals had DM for a decade. Regarding serious mental illness, 95 (48.0%) had a diagnosis of depression, 56 (28%) had a diagnosis of bipolar disorder, and 49 (24%) had a diagnosis of schizophrenia. On average, individuals had SMI for nearly two decades. The sample was comprised largely of very low income individuals. Insurance status illustrated the socio-economic status of our participants; participants Medicaid (47.5%), Medicare (34.5%), no insurance (14.5%), or private insurance (3.5%).

**Figure 1: Eligibility, Randomization and Follow-up Process in a Behavioral RCT involving individuals with Serious Mental Illness (SMI) and Diabetes (DM)**



Barriers to recruitment and retention

Building upon the multi-level level barrier model by Levkoff & Sanchez (2006) we conducted a study team survey to rank order of barriers to study recruitment and retention. First, the multidisciplinary clinical research team who conducted the recruitment and who were directly involved in the day to day recruitment and retention activities (SK, EFC, MA, KC) for the study independently identified barriers experienced by SMI-DM study participants in the RCT. The barriers were identified based upon conversations and interactions with study participants regarding potential problems with attending intervention sessions and/or study visits. The list of barriers was then collated and staff independently ranked the barriers in terms of how common a problem they perceived each barrier to be on both recruitment and retention. Rankings were categorized along a continuum of “very common”, “somewhat common” or “not common”. Barriers were rank-ordered by summing scores for the number of “very common”

barrier endorsements (3 points per endorsement) and “somewhat common” barrier endorsements (2 points per endorsement) and arriving at average score. Study staff also independently identified how they or other members of the study team addressed each of the barriers during the course of the RCT. Finally, using a group consensus process, the barriers were grouped into categories conceptualized in terms of environment/societal (Macro), healthcare system/public services (mediator), and individual (symptoms, personal attitudes).

## RESULTS

### Retention vs. Non-retention Sample

200 individuals were enrolled in the study. Table 1 illustrates demographic and clinical characteristics of those who were retained (N=150, 75.0%) vs. those who were not retained (N=50, 25.0%) at the 60-week follow-up. There were no significant differences in retained vs. not-retained individuals on any of the baseline demographic or clinical variables assessed in this analysis including age, gender, race/ethnicity, SMI diagnosis or DM control was evaluated with with HbA1c which represents a rolling average blood glucose level over the previous 3 months. The American Diabetes Association (ADA) recommends that HbA1c should be < 6.5% (American Diabetes Association, 2013).

**Table 1: Demographic and Clinical Characteristics of individuals with SMI and DM retained vs. not retained at 60 week follow-up in a behavioral RCT.**

<b>VARIABLE</b>		<b>Retained at 60 weeks N=150</b>	<b>Not Retained N=50</b>	<b>p-value*</b>
<b>Age Mean(SD)</b>		55.67 (9.8)	54.05 (7.7)	0.11
<b>Gender N (%)</b>	<b>Male</b>	49 (32.9)	23 (45.1)	0.13
	<b>Female</b>	100 (67.1)	28 (54.9)	
<b>Ethnicity (Hispanic) N (%)</b>	<b>Hispanic</b>	13 (8.7)	4 (7.8)	1.00
	<b>Not Hispanic</b>	136 (91.2)	47 (92.2)	
<b>HbA1c Mean (SD)</b>		7.87 (2.2)	8.37 (2.6)	0.48
<b>Race N (%)</b>	<b>African American</b>	83 (55.0)	24 (49.0)	0.53
	<b>Caucasian</b>	54 (35.8)	20 (40.8)	
	<b>Other</b>	14 (9.3)	5 (10.2)	
<b>SMI diagnosis N (%)</b>	<b>Schizophrenic/ Schizo-affective Disorder</b>	39 (25.3)	(21.7)	0.71
	<b>Bipolar Disorder</b>	40 (26.6)	15 (32.6)	
	<b>Depression</b>	74 (48.1)	21 (45.7)	

\*Wilcoxon test done for continuous and chi-square test for categorical variables

**Barriers to Recruitment and Retention**

Table 2 illustrates relative rank order of barriers to recruitment and retention. The most frequent barrier for recruitment was not having telephone access (phone disconnected and/or not having a current alternative working phone number on record with the health system or study). Additional top barriers to recruitment were transportation difficulties (eg., access to a vehicle, relying on public transportation, cumbersome public transportation routes, or not having money for parking or bus fares), co-morbid chronic physical health problems and schedule conflicts (eg., childcare availability conflicting with appointment time, or work schedule). Similar to recruitment, the most common barrier to retention was not having telephone access. Additional top barriers to retention included co-morbid physical health problems, inclement weather, transportation difficulties, schedule conflicts and family stress. As opposed to extant literature, our study did not find cultural, racial, or ethnic barriers to recruitment or retention to be a major barrier. Overall, the barriers to recruitment and retention were fairly similar.

**Table 2: Relative frequency\* of barriers to research study recruitment and retention among people with SMI and DM**

<b>Barrier</b>	<b>Barrier to Recruitment</b>	<b>Barrier to Retention</b>
Phone disconnected	1	1
Transportation difficulties	2	3
Chronic physical health problems	2	2
Schedule conflicts	2	3
Acute health issues	3	4
Mental health issues	3	5
Weather	4	2
Disagreed with SMI diagnosis	5	**
Stress from family or living circumstance	6	3
Potential subjects unaware he study	6	**
Providers not referring patients due to competing demands	7	**

\* Frequency rankings based upon total scores of relative weighting for “very common” and “somewhat common” barrier categorization.

\*\*These barriers were not noted to be relevant to retention as these individuals did not enroll in the study.

**Managing barriers to recruitment and retention along multiple levels**

As noted in Table 3, the vast majority of barriers to recruitment and retention within the participants occurred at the micro (individual) level and those barriers that RCT staff identified as being generally most common (telephone access, physical health, schedule conflicts) were also at the individual/micro level. Important barriers that were relevant at the macro/environmental level were weather and limited provider referrals, while a key barrier at the mediator/community level was difficulty with transportation.

Table 3 illustrates study procedures and methods that were used to minimize barriers as well as personnel strategies that were intended to target barriers. Given the relatively long (60-week) follow-up many of the personnel strategies in particular were repeated on a regular and relatively frequent basis.

**Table 3: Strategies to address multiple-level barriers to recruitment and retention of individuals with SMI and DM in a behavioral RCT**

Barrier by Level	Procedural/methodological strategies	Personnel strategies
<b>Macro Level</b>		
Weather	Re-schedule assessments, postpone group sessions until most severe weather passed.	
Providers not referring patients	Study presented annually to new medical trainees, and to faculty at regular meetings	Primary care provider co-investigators served as “Recruitment Champions” to promote referrals
Potential subjects unaware of study	Flyers at community mental health centers and throughout community	CTSA Community Outreach
<b>Mediator Level</b>		
Transportation difficulty	Provided roundtrip bus tickets, validated parking, scheduled assessments on days that participants had existing clinic appointment	
Stigma	Letters mailed to individuals referred to a study of DM, with no mention of SMI	Discuss SMI as a chronic disease similar to DM
<b>Micro-level</b>		
Phone disconnected	Use EHR to update contact information, repeated call attempts, contact authorized secondary contact person, mail letters to participants requesting that they contact the study staff	
Chronic physical health problem	Scheduled assessments around participants existing clinic appointments, flexible scheduling of assessments, telephone assessments if needed, assessment scheduling window of +/- 2 weeks of target date	
Schedule conflicts	Flexible appointment times to accommodate participant’s schedule,	

Barrier by Level	Procedural/methodological strategies	Personnel strategies
	scheduled assessment around participants existing clinic appointments, scheduling window allowing +/- 2 weeks of target date for assessment.	
Acute health issues	Reschedule assessment	
Mental health issues	Refer to a mental health provider, If necessary, conduct assessment by phone	Continuity of experienced, dedicated, empathetic and encouraging study staff
Disagreed with SMI diagnosis	Explanation of SMI and DM as chronic illnesses, did not focus on specifics of mental health diagnosis	Social support from study team members
Financial	\$25.00 stipend for assessment visits, round trip bus pass or parking validation, flexible scheduling for assessments to allow for jobs, provided diabetic-appropriate snacks which participants may not have been able to afford at assessment visits and TTIM sessions	
Stigma	For those attending the TTIM intervention, hearing PEs and participants discuss SMI helped those who were initially reluctant to join the discussions	
Stress from family or living circumstance	Flexible scheduling	Social support from study team members; problem identification and solving skills and practice for TTIM intervention participants.
Cultural or language barrier	Encourage questions, PEs were of diverse backgrounds	Bi-lingual Spanish/English research assistant for participants more comfortable conversing in Spanish.* Project staff were trained and had on-going discussions with the team regarding cultural competency and awareness.

\*Ability to speak and understand English was an inclusion requirement because the TTIM intervention was only available in English

## DISCUSSION

This RCT testing a novel behavioral treatment for SMI and comorbid DM recruited a sample of 200 individuals over a 28 month period and retained 75% of these individuals at 60-week follow-up. The 25% attrition rate in this RCT falls within the 25-60% rates reported in

previous literature (Sobell 1987, Morissey 1990). Crisante et al (2014) report that a study attrition rate of 33% and 52% was observed at the 6-month and 12-month follow-up research interviews, respectively, of 1289 subjects who had mental illness and were diverted from jail. There were no statistically significant differences in baseline characteristics between those who were retained at 60-week follow-up vs. those who were not retained.

Barriers to recruitment and retention were similar to those described in Hughes Morley et al's (2015) systematic review and meta-synthesis of factors effecting recruitment to depression trials. This article is the first the authors are aware of that discusses barriers to recruitment and retention among individuals with depression, schizophrenia, or bipolar disorder and DM. Morley's review, however, did not offer suggestions for work-arounds to overcome barriers. The main problem we found regarding both research enrollment and retention of individuals with SMI and DM was poor telephone access. While many individuals had mobile telephones, most individuals had only limited minutes/talk time on their phones, and it was very common for minutes to run out, leaving the individual inaccessible to study staff. Additionally, there is increasing use of inexpensive (throw-away) cellular phones with minutes plans, resulting in some individuals replacing phones (and associated phone numbers) frequently. Other key barriers to study enrollment and retention were problems with transportation, chronic health problems which prevented the individual from making or keeping research appointments and personal schedule conflicts.

The study staff used a variety of methods to overcome or work around barriers to recruitment among individuals with SMI and comorbid DM. On the macro/environment level, study staff presented the study to trainees and faculty on a regular basis. Two of the study investigators served as "Recruitment Champions", meeting with faculty to encourage them to provide patient referrals and distributing study recruitment fliers. A major boost to recruitment was using the electronic health record (EHR) to identify potential study candidates. With appropriate IRB approval, individuals were sent letters inviting them to hear more about the study (opt-out was a clearly available choice) and the letters were followed up with a telephone call for individuals that chose not to opt out. Stigma of mental illness can effect study recruitment and retention. We found work-arounds at the micro- and mediator- levels (Table 3). To address mediator level barriers such as stigma, we utilized study staff with extensive mental health expertise and an informed consent process that was specifically tailored to individuals with cognitive and health literacy limitations; letters regarding the study did not mention mental illness; and we discussed mental illness as a chronic medical condition similar to diabetes. Bus passes and parking re-imbursement helped address transportation difficulties for a number of individuals.

To address the micro/individuals level barrier of poor telephone access, the electronic medical record was checked to update contact information among subjects who were patients of the health system. The health system routinely ask patients to provide up-to-date contact information at clinical encounters.

Some individuals were able and willing to provide contact information for family members or other supports at baseline who could serve as alternative contacts. Unfortunately, this was not always available for some individuals with SMI, who were socially isolated and estranged from family.

As demonstrated by our rate of attrition, retention of individuals with SMI and comorbid DM was a challenge. As with recruitment procedures, potentially helpful strategies at the micro,

mediator, and macro levels included both study procedures and personnel activities to optimize retention. Strategies such as using the electronic health record to update contact information was particularly critical as was continued provision of support for transportation. Although our study was limited to English-speakers, having bilingual Spanish-speaking staff helped Hispanic participants who prefer speaking Spanish feel comfortable in asking questions or asking for clarification in Spanish. Flexibility in format and timing of assessments was helpful in accommodating individuals who were prone to recurrent serious medical issues as well as family/social stress.

The barriers and work-arounds described in this article may not be generalizable due to its' relatively small sample size, single site in an urban area, and reliance on the clinical research team who conducted the recruitment and retention activities for identifying and ranking barriers. A limitation of this study is that it does not address systemic/societal barriers that contribute to barriers on the individual level. The purpose of this paper is to identify tangible day-to-day barriers and offer potential solutions or work-arounds to overcome the barriers. Thus, the authors focus on recognizing individual barriers that could be addressed by researchers in future studies with this type of participant population.

## CONCLUSIONS

Recruitment and retention of individuals with SMI and comorbid DM in research studies can be challenging, with major impediments being telephone contact and logistic difficulties due to lack of transportation and significant medical complications. Future researchers, when planning studies involving patients with SMI and multi-morbidity may want to consider implementing strategies highlighted in Table 3 to overcome or work-around barriers. Strategies to address recruitment and retention barriers can be helpful although additional work that includes SMI participant input is needed to better address how best to address barriers to research study participation.

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## REFERENCES

- American Diabetes Association, 2013. Standards of medical care in diabetes--2013. *Diabetes Care* 36 Suppl 1, S11-66.
- Atwood, J. R., Haase, J., Rees-McGee, S., Blackwell, G., Giordano, L., Earnest, D., ... & Meyskens Jr, F. (1992). Reasons related to adherence in community-based field studies. *Patient education and counseling*, 19(3), 251-259.
- Bartels, S. J., Pratt, S. I., Aschbrenner, K. A., Barre, L. K., Naslund, J. A., Wolfe, R., ... & Bird, B. L. (2014). Pragmatic Replication Trial of Health Promotion Coaching for Obesity in

- Serious Mental Illness and Maintenance of Outcomes. *American Journal of Psychiatry*: 1-9 doi: 10.1176/appi.ajp.2014.14030357
- Crisanti, A. S., Case, B. F., Isakson, B. L., & Steadman, H. J. (2014). Understanding study attrition in the evaluation of jail diversion programs for persons with serious mental illness or Co-occurring substance use disorders. *Criminal Justice and Behavior*, doi 0093854813514580.
- Daumit, G.L., Goldberg, R.W., Anthony, C., et al (2005) Physical activity patterns in adults with severe mental illness. *The Journal of Nervous and Mental Disease* 193:641-646.
- Daumit, G.L, Dickerson, F.B., Wang, N.Y., et al, (2013) A behavioral weight-loss intervention in persons with serious mental illness. *The New England Journal of Medicine* 368:1594-1602.
- Dipasquale, S., Pariante, C. M., Dazzan, P., Aguglia, E., McGuire, P., & Mondelli, V. (2013). The dietary pattern of patients with schizophrenia: a systematic review. *Journal of psychiatric research*, 47(2), 197-207.
- Dembling, B. P., Chen, D. T., & Vachon, L. (1999). Life expectancy and causes of death in a population treated for serious mental illness. *Psychiatric Services*, 50(8), 1036-1042.
- The Diabetes Prevention Program Research Group (2000) The Diabetes Prevention Program: baseline characteristics of the randomized cohort. *Diabetes Care* 23(11):1619-1629.
- Harris, P.A., Taylor. R., Thielke, R. et al, (2019) Research electronic data capture (REDCap) - A metadata-driven methodology and workflow process for providing translational research informatics support. *Journal of Biomedical Informatics* 42(2):377-81.
- Hughes-Morley, A., Young, B., Waheed, W., Small, N., & Bower, P. (2015). Factors affecting recruitment into depression trials: Systematic review, meta-synthesis and conceptual framework. *Journal of affective disorders*, 172, 274-290.
- Jerome,G.J., Young, D.R., Dalcin, A, et al (2009) Physical activity levels of persons with mental illness attending psychiatric rehabilitation program.ms. *Schizophrenia Research* 108:252-25.
- Levkoff S, Sanchez H. (2003) Lessons learned about minority recruitment and retention from the Centers on Minority Aging and Health Promotion. *Gerontologist* 43(1):18–26.
- Loue, S., & Sajatovic, M. (2006). Spirituality, coping, and HIV risk and prevention in a sample of severely mentally ill Puerto Rican women. *Journal of Urban Health*, 83(6), 1168-1182.
- Loue, S., & Sajatovic, M. (2008) Research with severely mentally ill Latinas: Successful recruitment and retention strategies. *Journal of Immigrant and Minority Health* 10(2), 145-153.
- McKibbin CL, Patterson TL, Norman G, et al. (2006) A lifestyle intervention for older schizophrenia patients with diabetes mellitus: a randomized controlled trial. *Schizophrenia Research* 86:36-44, 2006.
- Miller, B.J., Paschall, C.B., 3rd, Svendsen, D.P. (2006) Mortality and medical comorbidity among patients with serious mental illness. *Psychiatric Services* 57:1482-1487. 17035569.
- Morrissey, J. P., & Dennis, D. L. (1990). *Homelessness and mental illness: toward the next generation of research studies: proceedings of a NIMH-Sponsored Conference, Bethesda, Maryland, February 21 and 22, 1989*. National Institute of Mental Health.
- Murry VM, Kotchick BA, Wallace S et al. (2003) Race, culture, and ethnicity: Implications for a community intervention. *Journal of Child and Family Studies*, 13:81–99.

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- Sheehan, D. V., Janavs, J., Baker, R., Harnett-Sheehan, K., Knapp, E., Sheehan, M., ... & Lepine, J. P. (1998). MINI-Mini International Neuropsychiatric Interview-English Version 5.0. 0-DSM-IV. *Journal of Clinical psychiatry*, *59*, 34-57.
- Sobell, M. B., Brochu, S., Sobell, L. C., Roy, J., & Stevens, J. A. (1987). Alcohol treatment outcome evaluation methodology: State of the art 1980–1984. *Addictive Behaviors*, *12*(2), 113-128.