



# Tailored strategies to engage vulnerable populations in clinical research in Northern Health

Roseann Larstone, Ph.D. and Sarah Gray, Ph.D.  
Northern Medical Program, University of Northern British Columbia

Presentation to the Northern BC Research and Quality Conference  
November 7, 2018



# Faculty/Presenter Disclosures

Nothing to disclose

# Research Team – CIMI Study

**Dr. Sarah Gray**, Principal Investigator, Northern Medical Program, UNBC

**Dr. Candida Graham**, PI, NMP, UNBC (former Co-PI)

**Dr. Roseann Larstone**, Research Associate, NMP UNBC

UBC Psychiatry Residents:

**Dr. Christine Kennedy**

**Dr. Eric Paulsen**

**Dr. Michelle Waller**

Research Technicians:

**Aashka Jani**

**Dr. Saurabh Parmar**

**Sabrina Trigo**      Administrator: **Lindsay Mathews**



# Research Network

**Early Psychosis Intervention (EPI) Program**

**University Hospital of Northern BC**

**Northern Health**

Dr. B. Griffiths, Psychiatrist, NH

Dr. D. Zanozin, Psychiatrist, NH

**Clinical Team:** Chantelle Wilson (Manager, Child & Youth Specialized Services), Sandi DeWolf; (EPI Team Lead), Chris Painter; Deryl Henderson; Josh van der Meer; Melanie Cailleaux; Vanessa Kinch

Former EPI team members: Mary Morrison; Al Aben; Kim Allen; Darlene Bilous; Cliff Mann

## WHY IS THIS RESEARCH URGENT?

**20%**

**OF ADULTS**

**IN CANADA ARE  
AFFECTED BY  
MENTAL ILLNESS**

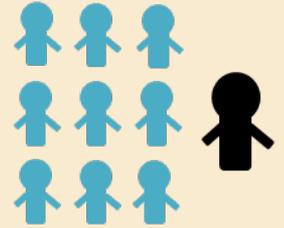
**15%**

**OF INDIVIDUALS  
EXPERIENCING  
SCHIZOPHRENIA  
have diabetes**

---

**425 MILLION  
PEOPLE  
GLOBALLY, &  
3.4 MILLION IN  
CANADA**

---



**Have type 2 diabetes**



**DIABETES AND OBESITY  
ARE LINKED TO HEALTH  
COMPLICATIONS LIKE  
HEART DISEASE AND  
STROKE**

# Background

- Reduce health inequities; vulnerable populations under-represented in research (UyBico et al., 2007)
- Recruiting sufficient sample sizes key (Newington & Metcalfe, 2014)
- Challenges in meeting recruitment goals common (Loue & Sajatovic, 2008; Newington & Metcalfe, 2014; Segre et al., 2011)
- Barriers to recruitment/retention (R/R) amplified when engaging vulnerable populations (Furimsky et al., 2008; Kanuch et al., 2016)
- Growing research focus on R/R (Kanuch et al., 2016; Segre et al., 2011; Snow et al., 2018)

# Background

- Recognize, anticipate & address potential barriers to R/R (Furimsky et al., 2008)
- Plan for R/R strategies during study development and implementation: one size does not fit all (Snow et al., 2018)
- Barriers at individual, family, societal/systemic, research levels (Andrighetti et al., 2017; Snow et al., 2018)

# Background

- **Individual-level** barriers: co-morbid physical/psychiatric symptoms; medication side-effects; language; social location; low motivation; low literacy/health literacy; contact insecurity; mistrust of research (Cunningham Erves et al., 2017; Western et al., 2016)
- **Family-level**: stress from family or living circumstances; low support of family members (Kanuch et al., 2016)
- **Social/systemic level**: employment status; stigma (Woodall et al., 2010)
- **Research level**: time commitments; transportation; complicated study protocols; scheduling; communication; discomfort with study procedures (Adams et al., 2015; UyBico et al., 2007)

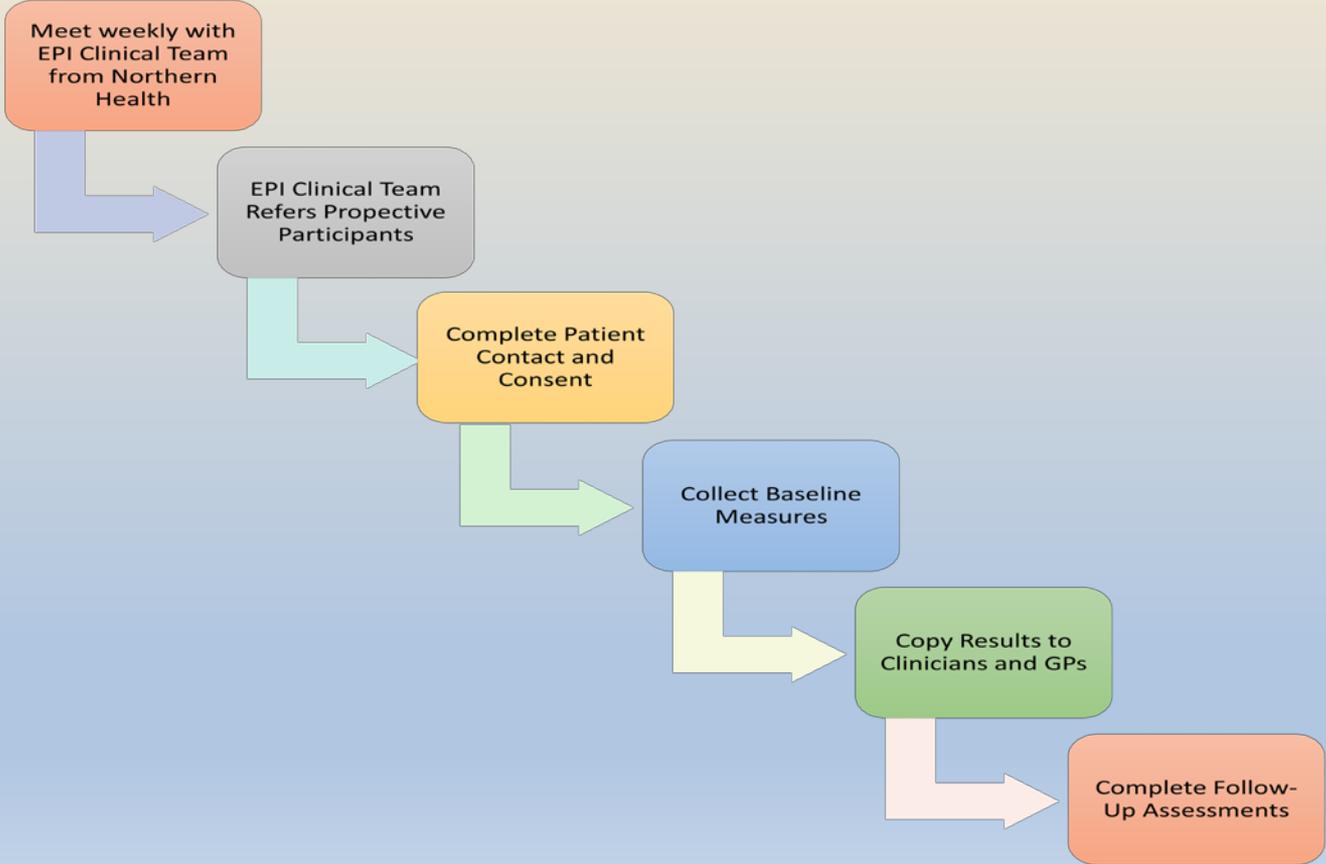
# Purpose

- Describe participant- and clinician-level research strategies and processes supporting participant recruitment and retention

# Methods

- Longitudinal, cohort design with a nested case-control study enrolling age- and gender-matched controls

# Study Process



# Methods

## **Inclusion criteria for clinic-referred participants**

- 1) being a patient of NHA, Mental Health and Addictions (MH&A) specialist teams in Prince George, B.C.;
- 2) diagnosed with first break psychosis in past 6 months;
- 3) between the ages of 19-45 years; and
- 4) a patient deemed stable enough for study inclusion by their MH&A case manager.

**Exclusion criterion:** a previous diagnosis of type 1 diabetes

# Measures – Baseline and Follow-up

## **Demographic data**

**Detailed family and patient history** (including medications; excluding personal and sexual history)

**Structured Clinical Interview for DSM-5 (SCID-5; Baseline only)** and the **Brief Psychiatric Rating Scale (BPRS)**

**Physical measures of cardiometabolic health** (blood pressure; height; weight; waist circumference; physical signs of dyslipidemia (arcus cornea, xanthelasma or xanthoma) or insulin resistance (acanthosis nigricans)

**Mood and health behaviors:** Patient Health Questionnaire (PHQ-9) and the Modified Health and Behavior Survey (MHBS)

**Blood - Standard biochemical measures of cardiometabolic & general health:** fasting lipid profile (triglycerides, total cholesterol, HDL, LDL (calculated)); fasting blood glucose; HgA1C; insulin; TSH; CBC; electrolytes; ALT, AST)

**Blood - Specialized biochemical measures of inflammation:** interleukin-6 (Il-6), tumor necrosis factor alpha (TNF- $\alpha$ ) and C-reactive protein (CRP) measured in plasma samples using ELISA (Alpco, Salem, NH). Blood collected by a certified laboratory and analyzed in Gray Lab (UNBC)

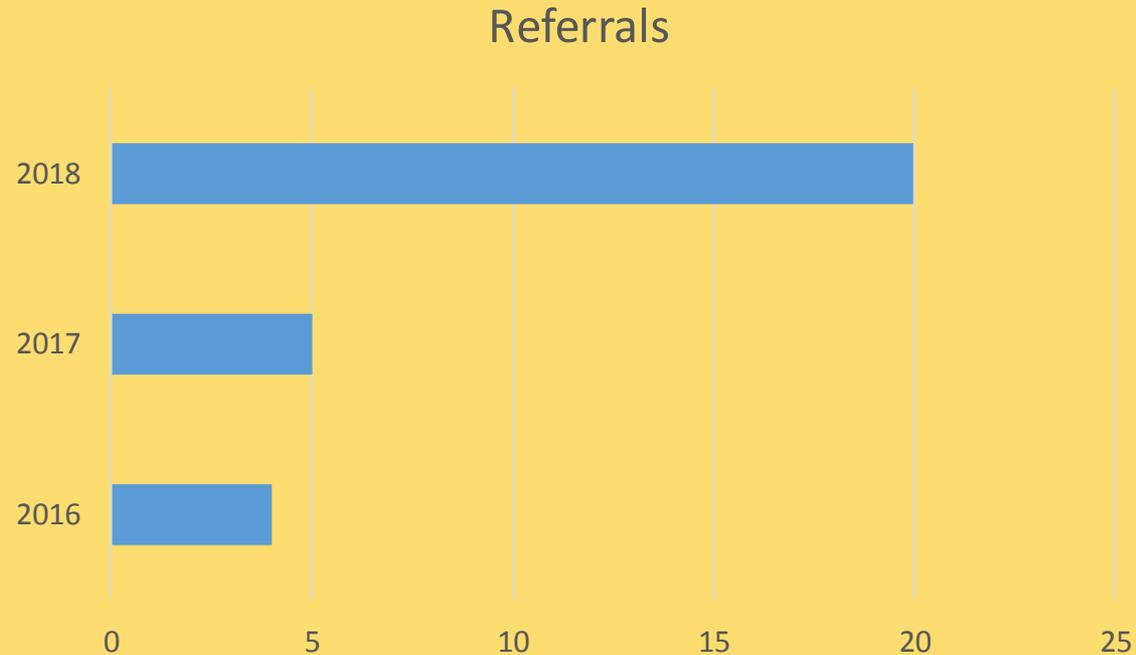
# Results

DEMOGRAPHICS	Baseline (n=21)	3-month (n=10)	6-month (n=9)	12-month (n= 4)	24-month (n= 1)
Gender	<i>n</i> (% of sample)	<i>n</i> (% of sample)	<i>n</i> (% of sample)	<i>n</i> (% of sample)	<i>n</i> (% of sample)
Male	13 (61.9%)	7 (70.0%)	6 (66.7%)	3 (75.0%)	1 (100%)
Female	8 (38.1%)	3 (30.0%)	3 (33.3%)	1 (25.0%)	0 (0%)
Age range	19-42 (mean <sub>age</sub> = 24.67)	19-33 (mean <sub>age</sub> =23.90)	19-33 (mean <sub>age</sub> =23.90)	21-34 (mean <sub>age</sub> =26.25)	age=24

# Results

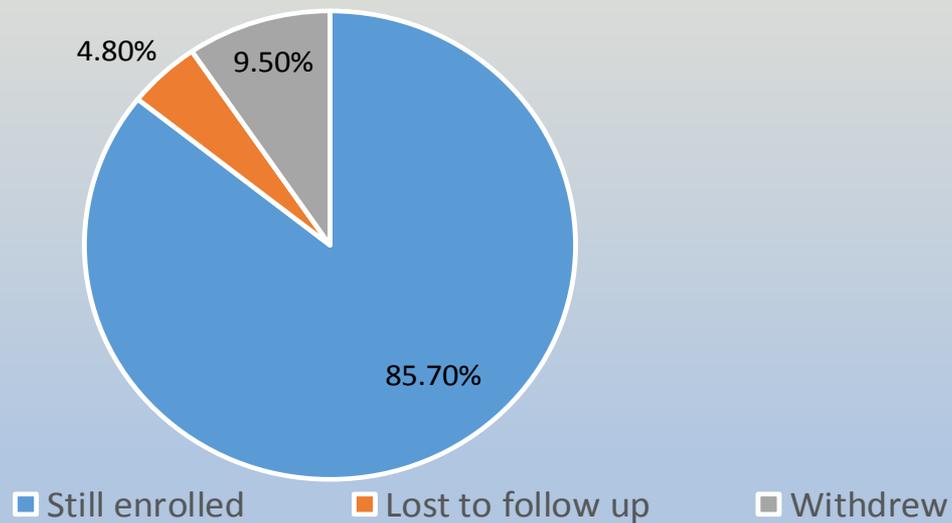
Summary of clinic-based referrals received (2016-2018)

Total referrals received in 2018: 20



# Results

## Retention



# Discussion

- **Clinician-level retention strategies:**
  - Collaborative stakeholder engagement
  - Communicating value of research
  - Knowledge translation
- **Participant-level:**
  - Minimize practical barriers
  - Communication; build trust; respect and inclusivity
- **Research-level:**
  - Study documents
  - Honoraria
  - Accessibility

# Significance

- R/R strategies in the context of research on cardio-metabolic disease risk in individuals with EMI
- Takeaway: non-hierarchical approaches and person-focused participant engagement essential

# Conclusions

- “Lessons learned” (Cunningham Erves et al., 2017)
- Attrition an ongoing challenge
- Limitations: generalizability

# Future directions

- Community engagement: develop patient-oriented research & identify patient-focused priorities, concerns and research needs

# References

- Adams, M. et al. (2015). Barriers and opportunities for enhancing patient recruitment and retention in clinical research: Findings from an interview study in an NHS academic health science centre. *Health Research Policy and Systems*, 13:8.
- Andrighetti, H., Semaka, A., & Austin, J. (2017). Women's experiences of participating in a prospective, longitudinal postpartum depression study: insights for perinatal mental health researchers. *Archives of Women's Mental Health*, 20, 547–559.
- Bradshaw, T. & Mairs, H. (2014). Obesity and serious mental ill health: A critical review of the literature. *Healthcare*, 2, 166-182, doi:10.3390/healthcare2020166
- Brown, S. et al. (2000). Causes of the excess mortality of schizophrenia. *The British Journal of Psychiatry*, 177, 212-217
- Canadian Diabetes Association Clinical Practice Guidelines Expert, C., Robinson, D. J., Luthra, M. & Vallis, M. (2013). Diabetes and mental health. *Canadian Journal of Diabetes*, 37 (S1), S87-92, doi:10.1016/j.cjcd.2013.01.026
- Correll, C. U. et al. (2014). Cardiometabolic risk in patients with first-episode schizophrenia spectrum disorders: Baseline results from the RAISE-ETP study. *JAMA Psychiatry*, 71, 1350-1363, doi:10.1001/jamapsychiatry.2014.1314
- Cunningham Erves, J. et al. (2017). Needs, priorities, and recommendations for engaging underrepresented populations in clinical research: A community perspective. *Journal of Community Health*, 42, 472–480.
- De Hert, M. et al. (2011). Physical illness in patients with severe mental disorders. I. Prevalence, impact of medications and disparities in health care. *World Psychiatry*, 10, 52-77.
- Furimsky, I. et al. (2008). Strategies to enhance patient recruitment and retention in research involving patients with a first episode of mental illness. *Contemporary Clinical Trials*, 29, 862–866.
- Holt, R. I. et al. (2005). Diabetes and schizophrenia 2005: Are we any closer to understanding the link? *Journal of Psychopharmacology*, 19, 56-65.
- International Diabetes Federation. <http://www.diabetesatlas.org/> (accessed Oct. 30, 2018).
- Kanuch, S., et al. (2016). Recruiting and retaining individuals with serious mental illness and diabetes in clinical research: Lessons learned from a randomized, controlled trial. *Journal of Health Disparities Research and Practice*, 9(3): 115–126.
- Khandaker, G. M. et al. (2014). Association of serum interleukin 6 and c-reactive protein in childhood with depression and psychosis in young adult life. *JAMA Psychiatry*, 71(10), 1121-1128.
- Klemettila, J. P. et al. (2014). Cytokine and adipokine alterations in patients with schizophrenia treated with clozapine. *Psychiatry Research*, 218, 277-283, doi:10.1016/j.psychres.2014.04.049
- Kunz, J. H. et al. (2010). Health-related quality of life of youth with inflammatory bowel disease: a comparison with published data using the PedsQL 4.0 generic core scales. *Inflammatory bowel Diseases*, 16, 939-946, doi:10.1002/ibd.21128

# References

- 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.
- Mezuk, B. et al. (2008). Depression and type 2 diabetes over the lifespan: a meta-analysis. *Diabetes Care, 31*, 2383-2390, doi:10.2337/dc08-0985
- Mitchell, A. J. et al. (2013). Prevalence of metabolic syndrome and metabolic abnormalities in schizophrenia and related disorders--a systematic review and meta-analysis. *Schizophrenia Bulletin, 39*, 306-318, doi:10.1093/schbul/sbr148
- Na, K. S. et al. (2012). Relationship between inflammation and metabolic syndrome following treatment with paliperidone for schizophrenia. *Progress in Neuro-Psychopharmacology & Biological Psychiatry, 39*, 295-300, doi:10.1016/j.pnpbp.2012.06.024
- Newcomer, J. W. (2007). Metabolic considerations in the use of antipsychotic medications: A review of recent evidence. *The Journal of Clinical Psychiatry, 68*(S1), 20-27.
- Newington, L., & Metcalfe, A. (2014). Factors influencing recruitment to research: Qualitative study of the experiences and perceptions of research teams. *BMC Medical Research Methodology, 14*:10.
- Nolte, E. & McKee, C. M. (2008). Measuring the health of nations: updating an earlier analysis. *Health Affairs, 27*, 58-71, doi:10.1377/hlthaff.27.1.58
- Nordentoft, M. et al. (2013). Excess mortality, causes of death and life expectancy in 270,770 patients with recent onset of mental disorders in Denmark, Finland and Sweden. *PLoS One, 8*, e55176, doi:10.1371/journal.pone.0055176
- Nousen, E. K. et al. (2013). Unraveling the mechanisms responsible for the comorbidity between metabolic syndrome and mental health disorders. *Neuroendocrinology, 98*(4), 254-266.
- Ouchi, N. et al. (2011). Adipokines in inflammation and metabolic disease. *Nature Review Immunology, 11*(2), 85-97.
- Ringen, P. A. et al. (2014). Increased mortality in schizophrenia due to cardiovascular disease - a non-systematic review of epidemiology, possible causes, and interventions. *Frontiers in Psychiatry, 5*, 137, doi:10.3389/fpsy.2014.00137
- Robson, D. & Gray, R. (2007). Serious mental illness and physical health problems: a discussion paper. *International Journal of Nursing Studies 44*, 457-466.
- Segre, L., Buckwalter, K., & Friedemann, M-L. (2011). Strategies to engage clinical staff in subject recruitment. *Journal of Research in Nursing, 16*(4): 321–332.
- Snow, M.E., et al. (2018). Heard and valued: The development of a model to meaningfully engage marginalized populations in health services planning. *BMC Health Services Research, 18*:181.
- Subramaniam, M. et al. (2003). Diabetes mellitus and impaired glucose tolerance in patients with schizophrenia. *Canadian Journal of Psychiatry. Revue Canadienne de Psychiatrie, 48*, 345-347, doi:10.1177/070674370304800512
- UyBico et al. (2007). Recruiting vulnerable populations into research: A systematic review of recruitment interventions. *Journal of General Internal Medicine, 22*, 852–863.
- Western, B. et al. (2016). Study retention as bias reduction in a hard-to-reach population. *PNAS, 113*, 5477-5485.
- Woodall, A. et al. (2010). Barriers to participation in mental health research: are there specific gender, ethnicity and age related barriers? *BMC Psychiatry 10*, 103. doi:10.1186/1471-244X-10-103



# Acknowledgements

- We thank our patient and control participants for their involvement in the CIMI study
- We thank Sandi DeWolf and all of the dedicated members of the EPI Clinical Team, Dr. Brenda Griffiths, and Lindsay Mathews for their clinical and administrative support of the project
- This research was supported by a Northern Medical Program Seed Grant to Drs. Gray and Graham, and UNBC Bridge Grant funding to Dr. Gray