Appendix A

INFORMATION SHEET AND INFORMED CONSENT FORM

Youth Version

Title of Research Study:
Among at-risk youth with mental health challenges, do integrated collaborative care teams provide more benefits in reducing symptoms, improving functioning and providing greater client satisfaction than treatment as usual?

What is the purpose of this study?
This study is comparing community service centers for youth to the usual treatment at CAMH. We want to find out if one of two types of services works better than the other in
(1) helping youth improve their symptoms and functioning
(2) satisfying youth and caregivers with the care experience
(3) reducing the cost to the healthcare system

What will I be asked to do as part of this study?
If you decide to participate in this study, you will be asked to do the following:

First assessment: All participants will attend a 1.5 hour meeting to agree to the study and complete some questionnaires. The purpose of the questionnaires will be to describe you, your symptoms, and how you’re doing in general. Your OHIP number and medical record number (MRN) will also be collected. This will let researchers track the health services you’ve used during the study to compare the cost of each type of treatment.

Second assessment: All participants will be interviewed for about 1 to 2 hours about a week after the first meeting. The purpose of the interview will be to give you the opportunity to describe you, your symptoms, and how you’re doing more in depth. The interview may be recorded to establish reliability, only to be heard by research team.

Services: After the first research meeting, you will be randomly assigned (like a coin toss) to either a community service center or CAMH. You will then meet with your new care providers and receive the services selected for you. Those receiving community services will be referred to a community service center offering a variety of mental health and addiction services for youth and their caregivers (mother, father, guardian). Those receiving CAMH services will meet with a CAMH professional and receive the services selected by that professional.

Six-month and twelve-months: You will be assessed again. The assessments will include some of the same questionnaires used at the beginning of the study, as well as questions about satisfaction and service use.

Chart review: We will also review your chart information at the site you are receiving services at.

What are the risks or harms of participating in this study?
We don’t expect much discomfort from participating in this study. Full services will be provided in both groups. However, answering the assessment may cause discomfort since some of the questions are personal. If you feel discomfort and wish to discuss it, the Research Assistant will help connect you to a mental health professional.
What are the benefits of participating in this study?
By participating in this study, you will be helping researchers by giving a youth’s perspective. Your participation will also help future patients by helping to shape the services offered to youth and their families.

Can participation in this study end early?
You can choose to end your participation at any time without having to provide a reason. If you choose to stop participating, you can continue to receive the same treatment; if you have been receiving treatment in the community and decide to leave the study, you can be referred back to CAMH by contacting the research team if you wish.

If you stop participating, the information already collected about you will still be used, but no more information about you will be collected. If you ask us to, we will destroy all the information we’ve already collected about you. The researchers may also end your participation at any time if they decide to.

Are study participants paid to participate in this study?
At each of the first two research meetings, you will receive a $25 gift card. At the third and fourth meeting, you’ll receive a $50 gift card.

How is confidential information handled?
The person looking at your file or contacting you must maintain your confidentiality to the extent permitted by law. For example, the law could make us give information about you if you or others have been abused. Other than that, only members of the research team will have access to your information. Your name and any other personal identifiers will not be used in any reports about this study.

As part of the quality assurance review of this research project, your study records might be assessed on behalf of the Research Ethics Board. A person from the CAMH research ethics team may contact you to ask questions about the research study and your consent to participate.

As part of the Research Services Quality Assurance Program, this study may be looked at by a member of the Quality Assurance Team. Your research records and your youth research and CAMH records may be reviewed. During this process, confidentiality will be maintained according to CAMH policies and the extent permitted by law.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

More information
You have the right to receive all important information that could help you make a decision about participating in this study. You also have the right to ask questions about this study and your rights as a research participant. If you have any more questions at any time, please feel free to contact Dr. Lisa Hawke, Ph.D., Project Coordinator, at 416-535-8501 ext. 39026, or Dr. Peter Szatmari, M.D., Researcher, at 416-535-8501 ext. 34029. If you have any questions about your rights as a participant in a research study, you may contact Dr. Padraig Darby, Chair, Research Ethics Board, Centre for Addiction and Mental Health, at 416 535 8501 ext. 36876.

Participant’s Initials: ____
Principal Investigator:
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CONSENT TO PARTICIPATE

**Study Title:** Among at-risk youth with mental health challenges, do integrated collaborative care teams provide more benefits in reducing symptoms, improving functioning and providing greater client satisfaction than treatment as usual?

**Name of youth participant:** ________________________________

I, ________________________________, have read (or had read to me) the Information Sheet for the study named above. My questions, if any, have been answered to my satisfaction.

I consent to participate in the study. I have been given a copy of this form to keep.

☐ I agree to be contacted for future studies at the contact number provided for this study.

☐ I do not agree to be contacted for future studies.

**Youth Participant:**

Name (print) ________________________________

Date (yyyy-mm-dd) ________________________________

Signature ________________________________

**Person Obtaining Consent:**

Name (print) ________________________________

Date (yyyy-mm-dd) ________________________________

Signature ________________________________