Preliminary evaluation of a “formulation-driven cognitive behavioral guided self-help (fCBT-GSH)” for crisis and transitional case management clients

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Background: Cognitive behavioral therapy (CBT) is found to be effective for common mental disorders and has been delivered in self-help and guided self-help formats. Crisis and transitional case management (TCM) services play a vital role in managing clients in acute mental health crises. It is, therefore, an appropriate setting to try CBT in guided self-help format.

Methods: This was a preliminary evaluation of a formulation-driven cognitive behavioral guided self-help. Thirty-six (36) consenting participants with a diagnosis of nonpsychotic illness, attending crisis and the TCM services in Kingston, Canada, were recruited in this study. They were randomly assigned to the guided self-help plus treatment as usual (TAU) (treatment group) or to TAU alone (control group). The intervention was delivered over 8–12 weeks. Assessments were completed at baseline and 3 months after baseline. The primary outcome was a reduction in general psychopathology, and this was done using Clinical Outcomes in Routine Evaluation – Outcome Measure. The secondary outcomes included a reduction in depression, measured using the Hospital Anxiety and Depression Scale, and reduction in disability, measured using the World Health Organization Disability Assessment Schedule 2.0.

Findings: Participants in the treatment group showed statistically significant improvement in overall psychopathology \((P<0.005)\), anxiety and depression \((P<0.005)\), and disability \((P<0.005)\) at the end of the trial compared with TAU group.

Conclusion: A formulation-driven cognitive behavioral guided self-help was feasible for the crisis and TCM clients and can be effective in improving mental health, when compared with TAU. This is the first report of a trial of guided self-help for clients attending crisis and TCM services.

Keywords: mental health crisis, transitional case management, cognitive behavior therapy, guided, self help

Introduction

Crisis services are now a well-established part of the mental health systems in North America.1 These programs have been found to be successful in improving access to mental health system for those with acute emotional or mental health problems and to help persons deal with a crisis. Crisis services are also a cost-effective way of reducing the costs of psychiatric hospitalization, as well as social costs, by providing professional assessment and crisis intervention in the community.2 There is evidence to suggest that the crisis services are associated with improved client satisfaction.2

Interestingly, most of the published research in this area is nearly two decades old.3 A recent Cochrane review reported that by supporting clients at their homes, the crisis teams can reduce repeat admissions to hospital. Crisis intervention also reduced...
family burden, and this was preferred by both clients and their families. However, the same review found no differences in mortality. The authors reported numerous methodological problems with the studies in this area. There is a lack of interventions in this area; for example, another Cochrane review failed to identify the impact of crisis intervention services for borderline personality disorders.

Crisis teams in different parts of the world operate differently. In Canada, the crisis teams work closely with the transitional case management (TCM) teams. Crisis teams in some countries work closely with home treatment teams. A number of investigations have also reported reduced length of in-client stay following introduction of crisis resolution and home treatment (CRHT). These studies suggest that in addition to reduced admissions, these teams reduce the duration of inpatient admissions and rates of detention. Using these services can catalyze a more efficient use of in-client care.

The CRHT, and TCM services offer an opportunity to provide evidence-based psychosocial interventions to improve well-being further and to prevent future relapses. However, there is currently no published literature on effective interventions within these services. Evidence-based self-help, guided self-help, and low-intensity psychological help can be easily provided in these setups. There is sufficient evidence in the form of meta-analyses and literature reviews to suggest that guided self-help can be as effective as the face-to-face treatments.

We, therefore, developed a “formulation-driven cognitive behavioral guided self-help (fCBT-GSH)” for common mental health problems that can be delivered by mental health professionals working in a crisis or TCM setting. This paper describes the preliminary evaluation of this intervention.

Methods
Study design
The study used a randomized controlled design to compare the efficacy of this fCBT-GSH plus treatment as usual (TAU) to TAU only within crisis and TCM services. The intervention is provided by trained mental health professionals for clients under care of the crisis and TCM service. The intervention group received fCBT-GSH and TAU, while the control group received TAU only. The TAU consisted of routine follow-up and care of the clients by crisis and TCM team. Both teams offer at least once a week face-to-face contact with the clients.

Recruitment and procedure
Client participants were recruited from crisis and TCM services in Kingston, Ontario. Current clients with a diagnosis of depression, anxiety, and other common mental health problems (using DSM-IV criteria) were considered eligible for inclusion, except for those using alcohol or drugs excessively or with significant cognitive impairment and those who were experiencing acute psychotic symptoms. Staff psychiatrists and case managers identified eligible clients.

Clients selected for the study were provided with brief information about the study. Those who met the criteria and consented in writing were then asked to join the study and were randomly allocated to one arm of the trial.

The Queen’s University Health Sciences & Affiliated Teaching Hospitals Research Ethics Board approved this study.

Participants
Randomization was performed using www.randomization.com. Out of 36 clients who completed the assessment phase and were subsequently randomized, eight dropped out of the study. Of these, three participants dropped out of the intervention group, and five from the control group.

Primary assessment measure
Psychopathology was measured using the Clinical Outcomes in Routine Evaluation – Outcome Measure (CORE-OM) and Hospital Anxiety and Depression Scale (HADS). Disability was measured using the World Health Organization Disability Assessment Schedule 2.0 (WHODAS 2.0). All the assessments were carried out at the baseline and after 3 months. Demographic and other details were measured using a form specially designed for the study.

The CORE-OM is a self-report measure tapping four domains, including a risk to others and risk to self. The scale was found to have good reliability, validity, and sensitivity to change. Each of the items (eg, “I have felt terribly alone and isolated”) is scored on a scale from 0 (Not at all) to 4 (Most or all of the time). It has been used in previous research to measure emotional disturbance in service settings delivering psychological interventions in primary and secondary care.

Secondary assessment measures
HADS
HADS is a rating scale comprised of 14 items, seven of which are designed to measure anxiety (HADS-A), and seven for depression (HADS-D). The HADS is a widely used measure of anxiety and depression, and its psychometric properties have been described in detail. Each of the items in HADS is scored on a four-point scale from 0 to 3. The item scores are summed to provide subscale scores on the HADS-D and the HADS-A, which may range between 0 and 21. Studies most commonly employ a cut-point of $\geq 8$ (eight and above) for each of the constituent subscales, as suggested by its authors, to indicate probable caseness.
WHODAS 2.0

WHODAS 2.0\textsuperscript{11} was developed by the WHO to measure disability due to physical and psychological problems. The scale was tested across the globe and was found to be both reliable and valid.\textsuperscript{11} Participants are asked to indicate how much difficulty they had in completing a certain task (eg, “Remembering to do important things”) in the last 30 days on a scale from 1 (None) to 5 (Extreme or cannot do). This instrument has been used extensively in research settings.

Therapists and treatment fidelity

A third-year psychiatry resident physician, two undergraduate psychology students, social workers, and other crisis team members, who had been trained in delivering CBT intervention, provided fCBT-GSH to the participants. Health professionals received training in using this intervention. This half-day training focused on the five basic areas CBT formulation. They were also educated on techniques described in handouts, eg, problem solving, behavioral activation, and use of thought diaries to recognize, challenge, and create alternative thoughts. They were not trained in delivering therapy as this intervention only required them to facilitate use of self-help. Standard aspects of cognitive therapy, different modules of fCBT-GSH manual, as well as home work assignments were also discussed. They also received weekly supervision. These meetings ensured adherence to the treatment protocol. During these meetings, sessions were reviewed and cases were discussed. Health professionals shared the formulation, barriers to home work, and difficulties in following handouts. These sessions typically lasted for 1–1.5 hours.

The intervention

There is sufficient evidence to suggest that self-help and guided self-help can be effective in helping mental and emotional health problems, specially anxiety and eating disorders.\textsuperscript{6,7} “Self-help” can be defined as:

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\text{[...]} \text{a therapeutic intervention that is based on a sound theoretical background, that uses therapeutic principles from an evidence-based intervention, and is administered through a “media” that does not involve direct contact with another person.}\textsuperscript{13}
\]

The “guided self-help” can be defined as “self-help that involves facilitation of the self-help by a lay person (eg, a carer) or by a health professional with minimum direct contact (\(<25\% \text{ of the normal therapy session time})\).” Contact between the clients and the other person can take place through face-to-face contact, by telephone, by email, or any other communication method.\textsuperscript{14}

This fCBT-GSH was developed by FN, who has previously adapted CBT for different cultures and settings.\textsuperscript{15–18} The intervention consisted of 24 handouts that could be flexibly used by a health professional. The intervention focused on psychoeducation, symptom management, changing negative thinking, behavioral activation, problem solving, improving relationships, and communication skills. The intervention consisted of essential worksheets (changing negative thinking and information sharing) plus worksheets that can be used flexibly according to a therapy plan that was driven on the basis of individuals’ particular needs. Therapy plan was based on a formulation. The intervention was delivered flexibly in that different sessions could be conducted by various team members, based on initial therapy plan. Where possible, carers were engaged in this process. A typical session consisted of feedback from the last week, a discussion of barriers, and information about the next handout. Table 1 provides further details.

Data entry and analysis

Analyses were carried out using SPSSv.22 (IBM Corp, Armonk, NY, USA). SPSS frequency and descriptive commands were used to measure descriptive statistics. SPSS explore command was used to measure normality of the data using histograms and Kolmogorov–Smirnov tests. Comparisons between the groups were made on an intention-to-treat basis. For an intention-to-treat analysis, participants were included in the groups to which they were randomized, regardless of whether they received the treatment allocated to them or not. All continuous variables (eg, the baseline questionnaire scores) were compared using paired \( t \)-tests, and categorical variables (eg, gender) were compared using \( \chi^2 \) tests. Differences in baseline and follow-up questionnaire scores between the two groups at the end of the intervention were compared using a linear regression.

Table 1 Salient features of the intervention

|   |   |
|---|---|
| 1. | Formulation-driven guided self-help, based on CBT, addressing common mental disorders. |
| 2. | An individual therapy plan prepared based on formulation and handouts given weekly using guided self-help. |
| 3. | Given flexibly to clients with a variety of problems. Guided self-help provided by different members of the team and not only by one dedicated therapist/worker. |
| 4. | Intervention consisted of 24 handouts that are given over 6–9 sessions per client on a weekly basis. |
| 5. | Intervention focuses on psychoeducation, symptom management, changing negative thinking, behavioral activation, problem solving, and improving relationships and communication skills. |
| 6. | Carers encouraged to be involved in helping the clients with therapy. |
| 7. | Team members provided with detailed guidelines in using the intervention, received half-day training in using intervention, and also supervised regularly. |

Abbreviation: CBT, cognitive behavioral therapy.
Results
A total of 63 clients were referred for the intervention. Out of 48 clients who fulfilled the inclusion criteria during the initial screening, 8 were excluded before baseline interviews were conducted, 4 refused immediately before baseline interview, and the remaining 36 were randomized to two groups. A total of 18 participants were randomized to the treatment group and 18 to the control group. The mean age of the participants was 34.6 (11.1). Of the 36 participants, 20 (55.6%) were female and 16 (44.4%) were male; 24 (66.7%) were single, 6 (16.7%) married, and 6 (16.7%) were divorced/widowed or widower. In terms of psychopathology, 3 (8.3%) participants had a diagnosis of an anxiety disorder, 3 (8.3%) of depression, 5 (13.9%) of post-traumatic stress disorder, social anxiety 9 (25.0%), mixed anxiety and depression 8 (22.2%), and panic disorder with agoraphobia 8 (22.2%). Table 2 provides additional differences on client variables, and Table 3 provides additional differences in psychopathology of the overall sample and between the intervention and control groups at baseline.

Those in treatment group showed statistically significant improvement in overall psychopathology (CORE) ($P<0.005$), anxiety and depression (HADS) ($P<0.005$), and disability (WHODAS 2.0) ($P<0.005$) at the end of the trial compared with those in TAU group. Table 4 describes these details.

Discussion
This study shows that a fCBT-GSH is feasible for crisis and TCM clients and can be potentially effective in improving mental health when compared with only TAU. This is the first report of an evaluation of guided self-help for clients attending crisis and TCM services. This is also the first study in which a cognitive behavioral guided self-help was delivered on the basis of the formulation.

This guided self-help was driven by formulation. Health professionals started by sharing the formulation with clients, and then developing a shared therapy plan. The case formulation is a vital element of CBT, along with assessment and intervention. It is considered to be the foundation on which therapeutic intervention is built. A good formulation is the hypothesis about the causes of the problems and why the problem persists. The formulation guides the treatment. It is, however, an ongoing process and can be done at various levels, from individual symptom to disorder. The formulation is the only way therapy can be individualized and provides an empirical approach to hypothesis testing.

### Table 2 Differences in client variables between the intervention and the control groups at baseline

| Client variables               | Total sample (N=36) | Intervention group (fg-CBT + TAU) (n=18) | Control group (TAU) (n=18) | P-value |
|--------------------------------|---------------------|-----------------------------------------|---------------------------|---------|
| Age (years)                    |                     | M (SD) 38.6 (11.1)                      | M (SD) 31.2 (7.78)        | 0.092   |
| Gender                         | Frequency           |                                      |                           |         |
|                               | Female              | 20                                     | 9                         | 0.502   |
|                               | Male                | 16                                     | 9                         |         |
| Ethnic group                   | Frequency           |                                      |                           | 0.261   |
|                               | White               | 32                                     | 16                        |         |
|                               | Black               | 1                                      | 0                         |         |
|                               | Asian               | 1                                      | 0                         |         |
|                               | Other               | 2                                      | 2                         |         |
| Relationship status            | Frequency           |                                      |                           | 0.174   |
|                               | Single              | 24                                     | 11                        |         |
|                               | Married/common law | 6                                      | 2                         |         |
|                               | Divorced            | 6                                      | 5                         |         |
| Education                      | Frequency           |                                      |                           | 0.927   |
|                               | High school         | 9                                      | 4                         |         |
|                               | College             | 25                                     | 13                        |         |
|                               | University          | 2                                      | 1                         |         |
| Employment                     | Frequency           |                                      |                           | 0.505   |
|                               | Employed            | 18                                     | 8                         |         |
|                               | Unemployed          | 18                                     | 10                        |         |
| Family history of mental illness| Frequency          |                                      |                           | 0.700   |
|                               | Yes                 | 27                                     | 13                        |         |
|                               | No                  | 9                                      | 5                         |         |

Abbreviations: fg-CBT, formulation-guided cognitive behavioral therapy; SD, standard deviation; TAU, treatment as usual.
Traditionally, however, self-help and guided self-help do not use a formulation-based approach, and mainly consist of a fixed manual. We therefore decided to use a formulation that was shared and agreed between the health professional and the clients based on the client’s specific needs. The therapy plan was agreed on the basis of this formulation. This helped us reach some level of an individualized approach.

The health professionals working with crisis and TCM services could use the current findings in several ways. This study shows that it is feasible to deliver CBT based self help and guided self help through the frontline clinicians. A formulation can help clients understand their problems in an easy to understandable language by linking their thoughts, emotions, physical sensations, and behaviors with the events in their lives. Such evidence-based interventions may motivate clients and give them hope and may also increase the clinician’s feelings of being effective in providing clients with an intervention. It is also highly likely that the health professionals will feel empowered and be more effective in helping their clients by having a better understanding of their problem as a result of the positive responses from patients.

**Limitations**

Several study limitations are noteworthy. This study recruited a small number of participants due to limited resources. Although these results raise hope that such low-cost interventions can become part of the routine care, caution is warranted as no prior power calculations were conducted for this pilot study. This is a new intervention, and ideally data on patient fidelity to different components of the intervention and its relation to treatment outcomes should have been conducted. This is especially important

### Table 3 Differences in psychopathology between the intervention and the control groups at baseline

| Psychopathology                              | Total sample (N=36) | Intervention group (fg-CBT + TAU) (n=18) | Control group (TAU) (n=18) | P-value |
|-----------------------------------------------|---------------------|------------------------------------------|----------------------------|---------|
|                                              | Frequency | %        | Frequency | %        |          |
| Diagnosis                                     | 0.283     |          | 0.283     |          |          |
| Anxiety disorder                              | 3        | 0.0      | 3        | 16.7     |          |
| Depression                                    | 3        | 11.1     | 1        | 5.6      |          |
| PTSD                                          | 5        | 22.2     | 1        | 5.6      |          |
| Social anxiety                                | 9        | 22.2     | 5        | 27.8     |          |
| Mixed anxiety and depression                  | 3        | 16.7     | 5        | 27.8     |          |
| Panic disorder with agoraphobia               | 3        | 16.7     | 5        | 27.8     |          |
| Drugs/alcohol                                 |          |          | 0.317     |          |          |
| Yes                                           | 17       | 58.8     | 7        | 41.2     |          |
| No                                            | 19       | 42.1     | 11       | 57.9     |          |

**Table 4 Linear regression analyses of differences between treatment and control groups, uncontrolled and controlled for initial differences**

| Clinical variables | TAU Mean (SD) | Intervention group (SD) | Differences uncontrolled for baseline | Differences controlled for baseline |
|--------------------|---------------|-------------------------|---------------------------------------|-----------------------------------|
|                    |               |                        | Mean difference (CI)                  | P-value                           |
| CORE-OM            | 64.8 (25.2)   | 35.7 (33.2)             | −29.06 (−49.03, −9.08)                | 0.006*                            |
| WHODAS 2.0         | 24.6 (12.7)   | 11.8333 (11.3)          | −12.72 (−20.9, −4.6)                 | 0.003*                            |
| HADS-D             | 9.17 (5.3)    | 4.4 (4.8)               | −4.8 (−8.2, −1.4)                    | 0.008*                            |
| HADS-A             | 9.3 (3.6)     | 3.9 (4.8)               | −5.3 (−8.2, −2.4)                    | 0.001*                            |

**Table 4 Linear regression analyses of differences between treatment and control groups, uncontrolled and controlled for initial differences**

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| WHODAS 2.0         | 24.6 (12.7)   | 11.8333 (11.3)          | −12.72 (−20.9, −4.6)                 | 0.003*                            |
| HADS-D             | 9.17 (5.3)    | 4.4 (4.8)               | −4.8 (−8.2, −1.4)                    | 0.008*                            |
| HADS-A             | 9.3 (3.6)     | 3.9 (4.8)               | −5.3 (−8.2, −2.4)                    | 0.001*                            |

**Notes:** *P<0.01, **P<0.05.

**Abbreviations:** CI, confidence interval; CORE-OM, Clinical Outcomes in Routine Evaluation – Outcome Measure; fg-CBT, formulation-guided cognitive behavioral therapy; HADS-A, Hospital Anxiety and Depression Scale: Anxiety Subscale; HADS-D, Hospital Anxiety and Depression Scale: Depression Subscale; PTSD, post-traumatic stress disorder; SD, standard deviation; TAU, treatment as usual; WHODAS, World Health Organization Disability Assessment Schedule 2.0.
since a formulation was the basis of this guided self-help. However, this was not possible due to limited resources. Future research should test this intervention in well-designed studies with adequate sample sizes.

Conclusion
This small scale study shows that CBT based self-help and guided self-help can be delivered by the front line clinicians working in crisis and TCM services. The intervention was found to be effective in reducing psychological distress and disability. This is however, only a small scale pilot study and there is a need to conduct large scale studies with improved methodology.

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