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Bachelor of Science in Medicine Degree Program
End of Term Final Report

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Project Title: An Evaluation of Large Group Cognitive Behaviour Therapy with Mindfulness (CBTm) Classes for Mood and Anxiety Disorders

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Summary (250 words max single spaced):
Background: Ensuring equitable and timely access to Cognitive Behaviour Therapy (CBT) is challenging within Canada's service delivery model. The current study aims to determine acceptability and effectiveness of 4-session, large, Cognitive Behaviour Therapy with Mindfulness (CBTm) classes. Methods: A retrospective chart review of adult outpatients with a mood or anxiety disorder (n=523) who attended classes from 2015-2016. Classes were administered in a tertiary mental health clinic in Winnipeg, Canada and averaged 30-40 clients per session. Primary outcomes were acceptability of the classes and retention rates. Secondary outcomes were changes in anxiety and depressive symptoms using Generalized Anxiety Disorder 7-item (GAD-7) and Patient Health Questionnaire 9-item (PHQ-9) scales. Results: Clients found classes useful and >90% expressed a desire to attend future sessions. The dropout rate was 26.3%. A mixed-effects linear regression demonstrated that classes improved anxiety symptoms (GAD-7 score change per class=-0.52 [95%CI, -0.74 to -0.30], P <0.001) and depressive symptoms (PHQ-9 score change per class=-0.65 [95%CI, -0.89 to -0.40], P <0.001). Secondary analysis found reduction in scores between baseline and follow-up to be 2.40 and 1.98 for the GAD-7 and PHQ-9, respectively. Effect sizes were small for all analyses. Conclusions: This study offers preliminary evidence suggesting CBTm classes are an acceptable strategy to facilitate access and to engage and maintain clients' interest in pursuing CBT. The classes are also effective in reducing symptoms of anxiety and depression. The clinical significance of symptom improvements remains unclear. Study limitations, such as a lack of control group, should be addressed in future research.

Student Signature

Primary Supervisor Signature

MD/PHD   MD/MSc.   BSc. (MED)   MED II Summer Research Program
Joe Doupe Annual Event   Undergraduate Medical Student Research Symposium

An Evaluation of Large Group Cognitive Behaviour Therapy with Mindfulness (CBTm) Classes for Mood and Anxiety Disorders

Introduction & Background

Each year, it is estimated that up to 3.5 million Canadians will access health services for a primary mood or anxiety disorder (Mcrae et al., 2016), and individuals with an anxiety disorder are known to be at an increased risk of developing a comorbid major depressive disorder (Katzman et al., 2014). These mental health conditions are associated with general medical conditions (Aquin et al., 2017; Gagnon & Patten, 2002), poor psychosocial functioning (Essau, et al., 2014; Kessler et al., 2003), and poor occupational functioning (Plaisier et al., 2010; Stewart, et al., 2003), leading to significant burden on both affected individuals and society (Wittchen, 2002). Canadian clinical practice guidelines list Cognitive Behaviour Therapy (CBT) as a first line treatment for both anxiety and major depressive disorders (Katzman et al., 2014; Parikh et al., 2016). CBT is an empirically based psychotherapy with robust evidence for the treatment of adult anxiety and depression (Butler et al., 2006; Cuijpers et al., 2013; Hofmann & Smits, 2008). CBT is based on identifying and shifting clients' dysfunctional cognitions and behaviours to reduce maladaptive emotions (Beck, 2011).

CBT is administered in diverse settings by a variety of health care practitioners including general practice physicians, psychiatrists, psychologists, nurses, and occupational therapists. Practitioners traditionally administer CBT to clients individually or in small group sessions, but ensuring equitable and timely access to CBT skills is challenging within this delivery model (Payne & Myhr, 2010). Poor access to treatment is a major issue precluding effective public health initiatives in anxiety and depression management, with a substantial proportion of individuals not receiving treatment despite a perceived need (Kohn et al., 2004; Mojtabai, 2009). Offering brief, low-intensity CBT within a stepped care model is one strategy aimed at improving CBT access in Canada (Parikh, 2015). Examples include self-help books, website based therapies, and, of particular interest to our study, large psychoeducational groups (Delgadillo et al., 2014). Administering CBT in a large-group is a promising solution which enables clinicians to reach a large number of clients.

Early research on large-group CBT suggests it may improve clients' anxiety symptoms more effectively than clients on wait-list (White, Keenan, & Brooks, 1992) or even small-group therapy (Brown et al., 1998). These initial findings are corroborated by recent UK studies demonstrating large-group interventions are efficient, well tolerated, and effective in treating symptoms of anxiety and depression (Burns et al., 2016; Delgadillo et al., 2016; Horrell et al., 2014). We identified the extant literature on large-group CBT has gaps regarding its acceptability and effectiveness in three areas: (1) North America, a region with limited government support for psychological therapies, (2) a tertiary care setting, and (3) the treatment of depression.

To address the gaps in the literature, we conducted a retrospective chart review of clients with anxiety and mood disorders who participated in 4-session, large, Cognitive Behaviour Therapy with Mindfulness (CBTm) classes. Previous work from our group showed similar 2-session CBT classes significantly reduced wait-times for conventional CBT group therapy in clients with anxiety disorders (Palay et al., 2017). We seek to expand these findings by investigating two primary outcomes: (1) acceptability and retention rates of CBTm classes and (2) clients' change in anxiety and depressive symptoms as a result of attending CBTm classes. Based on our previous work, we hypothesize the classes will be acceptable, both in terms of client feedback and retention rates. We also hypothesize our sample will experience

improvements in symptoms of anxiety and depression, replicating findings from the UK (Burns et al., 2016; Delgadillo et al., 2016; Horrell et al., 2014).

Materials & Methods

Participants

Clients who attended at least one CBTm class between January 2015 and December 2016. Clients were referred by general practice physicians to a centralized intake service within a tertiary care hospital in Winnipeg, Canada. From there, clients were referred to an outpatient mental health clinic for further assessment by a psychiatrist, psychiatry resident, or nurse therapist (referrals began in November 2014). Goals of the assessment were to confirm or establish a mental health diagnosis and to determine eligibility for the classes. Exclusion criteria for the classes are provided in Figure 1. It was deemed these factors would potentially prevent an individual from adequately concentrating and absorbing the class content. Alternative treatments were offered to ineligible clients as clinically indicated.

Intervention

CBT delivery followed a stepped care model. Our group of psychiatrists and clinical health psychologists independently developed and administered the CBTm classes to provide clients with self-help resources, basic CBT principles, and a head start in recovery. A corresponding website (cbtm.ca) was also developed. Classes were 90 minutes in length with an average of 30-40 clients per session and were led by two staff psychiatrists formally trained in CBT. Individuals were welcome to invite a partner, family member, or friend to accompany them. Class content was structured as follows:

- Class 1: introduction and outline of the course, rules and expectations, self-help resources, mindfulness exercise, introduction to the cognitive behavioural framework, cognitive distortions, thought records, and homework.
- Class 2: mindfulness exercise, review of homework, basics of behaviour therapy, exposure therapy, goal setting, and homework.
- Class 3: mindfulness exercise, review of homework, discussion of healthy living, sleep hygiene, and homework.
- Class 4: mindfulness exercise, review of homework, anger management strategies, assertiveness training, self-compassion, problem solving, and homework.

Following completion of 4 classes, clients were welcome to repeat classes as "booster sessions" or proceed to conventional CBT group therapy if more intensive treatment was required.

Procedure

The sample was derived from a retrospective chart review with approval from the University of Manitoba Human Research Ethics Board (H2015:137) and Research Impact Committee (R12015:048). Consent from each client was not required for this chart review. Measures were completed by every client on a session-to-session basis, immediately after each session, as part of routine monitoring of clinical progress. 'Sessions' included the initial intake assessment at the clinic, each CBTm class, and each small group CBT session following the classes (if applicable). The intake assessment served as the baseline and each subsequent

class attended in chronological order, regardless of intervention cycle, served as an individual time-point (up to a maximum of 4). The measures completed immediately before the first small group CBT session served as the study's follow-up. Classes were held weekly, with only slight variation due to clinician availability or holidays. The median wait time between the last attended class and follow-up was 9 weeks. This treatment gap was controlled for in relevant analyses.

Measures

Sociodemographic Factors and Dropout

Sociodemographic factors of interest (age, sex, marital status, education and employment) were obtained from a self-report questionnaire found in clients' medical charts. Clients completed this questionnaire on the day of their intake assessment at the clinic. The primary mental health diagnosis was also obtained from clients' medical charts, either through the CBTm class assessment form or other relevant notes and assessments completed at the intake assessment. Dropout data was obtained using class attendance forms completed at every class.

Acceptability and Baseline Predictors of Class Completion

Participants' self-reported acceptability of the CBTm classes was assessed using two items from the evaluation form they completed immediately after each session. The first item asks the respondent how useful they find the session and is rated on a 5-point Likert scale ranging between "1=Not very useful" and "5=Extremely useful". The second item is a dichotomous Yes/No question asking the respondent if they would attend another session like the one they just attended. GAD-7 score, PHQ-9 score, sex, education, and mental health diagnoses at the time of intake assessment were the baseline variables of interest in predicting completion of 4 or more classes.

Anxiety and Depressive Symptoms

The Generalized Anxiety Disorder 7-item (GAD-7) scale and the Patient Health Questionnaire 9-item (PHQ-9) scale were used to assess changes in anxiety and depressive symptoms, respectively. Both scales ask the respondent to reflect on how often they have been bothered by their symptoms over the past 2 weeks and rate items on a 4-point Likert scale ranging between 0="Not at all" and 3="Nearly every day". A large body of literature shows the GAD-7 and PHQ-9 to have good test-retest reliability and validity in measuring symptom severity in the general population (Kroenke et al., 2001; Lowe et al., 2008; Martin et al., 2006; Spitzer et al., 2006). These scales are also useful in monitoring symptom change across time (Lowe et al., 2008; Lowe et al., 2004; Spitzer et al., 2006). We applied McMillan et al.'s (2010) recommendations for both the GAD-7 and PHQ-9 to assess whether clients experienced clinically significant improvements in symptoms with the CBTm intervention. For anxiety this was defined as (a) mean GAD-7 score at follow-up <8 (Spitzer et al., 2006) (b) improvement greater than, or equal to, the minimum clinically important difference (MCID), and (c) meaningful associated effect sizes. For depression this was defined as (a) mean PHQ-9 score at follow-up <10 (Kroenke et al., 2001) (b) improvement greater than, or equal to, the MCID, and (c) meaningful associated effect sizes. The MCID is the smallest difference in score considered to be clinically important, and was determined to be 5 in our study for both the GAD-7 and PHQ-9 using Lowe et al.'s methodology (Lowe et al., 2004).

Analytic Strategy

Statistical analysis was performed using SPSS (version 24) and STATA (version 13.1). Descriptive statistics were obtained for the sample. The independent variable was the number of CBTm classes attended by a subject and the dependent variable was the score on the GAD-7 and PHQ-9. Primary analysis used a multi-level mixed-effects linear regression model to estimate the effect of the number of classes on the outcome measures. The model allowed the data to be analyzed as a within-subject design to examine the change in scores across repeated outcome measures in the same subject. The model controlled for the time between baseline and class 1, as well as the treatment gap between class 4 and follow-up during the first group session. This strategy more accurately estimates the relationship between exposure to each class and outcome measure scores by adjusting for potentially confounding time periods during therapy. Effect sizes (Cohen's *d*) of the regression model estimates were also obtained.

Secondary analysis calculated the mean differences in outcome measure scores between baseline and follow-up. Percent reductions in symptoms were calculated using the mean difference in outcome measure scores as the dividend and the mean baseline score as the divisor. Effect sizes (Cohen's *d*) of the mean differences were also obtained.

Adjusted odds ratios were calculated using a logistic regression model to assess baseline predictors of class completion. The variables of interest were regressed against a binary variable indicating completion of at least 4 classes.

Results

Sociodemographic factors and Dropout

Of the 655 participants assessed for eligibility for the CBTm classes from November 2014 to December 2016, 533 attended at least one class. The 122 participants who did not attend any class either chose not to for personal reasons or met exclusion criteria (Figure 1). Limited dropout information precludes us from providing further detail. Among those who attended, 393 (73.7%) completed 3 or more classes and 140 (26.3%) dropped out. We define dropout as completing less than 3 classes, regardless of reason for dropout. The mean number of classes attended by this sample was 3.5 (SD=1.7). 179 participants (53.8% of those eligible) moved on to receive small group CBT. The mean age of the analyzed sample was 39.3 (SD=13.8), and more than half were female (58.9%). At the intake assessment, the number of participants diagnosed with a primary anxiety or mood disorder were 253 (48.4%) and 214 (40.9%), respectively (Table 1).

Acceptability and Baseline Predictors of Class Completion

Mean scores on the usefulness item ranged between 3.9 and 4.1 (SD range=0.80 to 0.89). The proportion of participants who indicated they would attend another session was consistently over 90%, with a range of 94% to 99%, depending on the session. Two significant baseline predictors of CBTm class completion were found after adjusting for other variables. First, participants with a higher baseline score on the PHQ-9 were significantly less likely to complete 4 classes (OR=0.95 [95%CI 0.91 to 0.99], *p* <0.05). Second, participants who did not complete high school (did not graduate and/or receive diploma) were also significantly less likely to complete 4 classes (OR=0.39 [95%CI 0.20 to 0.75], *p* <0.05). All other baseline variables (GAD-7 score, sex, type and number of mental health diagnoses) did not significantly predict class completion.

Anxiety Symptoms

The mean baseline score for anxiety symptom severity was GAD-7=12.6 (SD=5.8). The mixed-effects linear regression indicated a statistically significant decline in symptoms of anxiety when attending CBTm classes (mean GAD-7 score change per class=-0.52 [95%CI, -0.74 to -0.30], p <0.001). The Cohen's effect size for this analysis was d=0.36, a small effect (Sawilowsky, 2009). This analysis controlled for the significant decline in symptoms between baseline and the first class, and the non-significant increase in symptoms between class 4 and follow-up (Table 2).

The mean change in the GAD-7 score between baseline and follow-up was -2.40 (95%CI, -3.38 to -1.41) – an 18% (95%CI, 9%-24%) reduction in anxiety symptoms (Table 3). The Cohen's effect size for this analysis was d=0.41, a small effect.

Depressive Symptoms

The mean baseline score for depression symptom severity was PHQ-9=15.2 (SD=6.8). The mixed-effects linear regression indicated a statistically significant decline in symptoms of depression when attending CBTm classes (mean PHQ-9 score change per class=-0.65 [95%CI, -0.89 to -0.40], p <0.001). The Cohen's effect size for this analysis was d=0.38, a small effect (Sawilowsky, 2009). This analysis controlled for the significant decline in symptoms between baseline and the first class, and the significant increase in symptoms between class 4 and follow-up (Table 2).

The mean change in the PHQ-9 score between baseline and follow-up was -1.98 (95%CI, -3.13 to -0.83) – a 13% (95%CI, 3%-18%) reduction in depressive symptoms (Table 3). The Cohen's effect size for this analysis was d=0.29, a small effect.

Discussion

The current study demonstrates that a 4-session, large, Cognitive Behaviour Therapy with Mindfulness (CBTm) class intervention is acceptable and effective in improving anxiety and depressive symptoms. To our knowledge, this is the first study to investigate large group CBT in a sample of Canadian individuals with mood and anxiety disorders. Our findings expand upon previous work from our group which found large group CBT classes delivered in a tertiary care setting reduce wait times for conventional CBT group therapy (Palay et al., 2017).

Our first hypothesis that the CBTm classes would be acceptable, both in terms of client feedback and retention rates, was supported by the results. Clients reported they found the classes useful and a significant proportion (over 90%) indicated they would attend another session. These findings remained stable through the 4 sessions, suggesting the classes are a viable strategy to facilitate CBT access and to engage and maintain the interest of a large number of clients. Successful engagement is a key advantage of this service delivery model as traditional CBT delivery often fails to provide clients with equitable and timely access to CBT skills at their time of most need.

Client retention further demonstrates the intervention's acceptability. The dropout rate was 26.3%, which is consistent with similar large group CBT interventions found in the literature (Burns et al., 2016; Delgadillo et al., 2016; Fernandez et al., 2015; Palay et al., 2017). It is important to highlight that we expected dropout – the CBTm classes were designed and implemented as a quality improvement initiative to reduce wait times and offer a head start in recovery for clients. We anticipated some clients would achieve symptom improvement or

remission at earlier stages and not require the 'complete' 4-session intervention. Taking this into consideration, having over 70% of clients attend all 4 classes is acceptable. More than half (53.8%) of eligible clients moved onto conventional small group CBT therapy. Future research should investigate long-term dropout rates and specific reasons for dropout as these were not assessed in this study.

Our second hypothesis that clients would experience improvements in anxiety and depressive symptoms was supported by the results, although effects were small. Primary analysis showed statistically significant improvement in both anxiety and depressive symptoms, with small effect sizes (d=0.36 and d=0.38 for anxiety and depressive symptoms, respectively). Our effect sizes are smaller than those reported in recent UK studies investigating large-group CBT (Delgadillo et al., 2016; Horrell et al., 2014). The first study was a randomized controlled trial showing that a one-day large CBT workshop had a medium effect in reducing depressive (d=0.55) and anxiety symptoms (effect size not reported) 12 weeks post intervention (Horrell et al., 2014). The other study investigated a 6-session large-group CBT intervention across 5 services over time. Investigators reported similar values in improving short-term depressive (d=0.59) and anxiety symptoms (d=0.70) (Delgadillo et al., 2016). Our smaller effect sizes make it unclear if clients attending the CBTm classes achieved clinically significant improvements in symptoms.

Secondary analyses revealed similar findings. The mean improvement of 2.40 on the GAD-7 and 1.98 on the PHQ-9 are not clinically significant according to Mcmillan et al.'s (2010) definition. They define successful treatment outcome for the PHQ-9 as a post-treatment score below the clinical threshold and improvement greater than or equal to the minimum clinically important difference (MCID). We followed their conservative definition in our study and applied it to the GAD-7 as well. Looking at our results, the mean improvement of 2.40 on the GAD-7 and 1.98 on the PHQ-9 did not meet the MCID of 5 that we determined for both measures. This improvement corresponds with post-treatment scores of 10.2 and 13.2 for the GAD-7 and PHQ-9, respectively. These scores suggest clients still experienced clinical symptom levels following the CBTm classes (Kroenke et al., 2001; Spitzer et al., 2006).

Our modest effect sizes may be partially explained by the length of the CBTm intervention and sample characteristics. In regards to length, four 90 minute sessions is brief when compared to formal CBT programs (Parikh et al., 2016) and the extant literature on large-group CBT discussed above (Delgadillo et al., 2016; Horrell et al., 2014). Dosing of psychotherapy is an important factor which influences efficacy, thus the brevity of our intervention makes the smaller effect sizes understandable. In terms of sample characteristics, our sample had slightly greater baseline anxiety and depressive symptom severity compared to extant literature (Delgadillo et al., 2016; Horrell et al., 2014). In fact, participants with more severe baseline depression or lower education were more likely to dropout. This is consistent with recent literature which demonstrates greater depression severity and low education are associated with poorer outcomes in low intensity psychotherapy (Delgadillo et al. 2016; Fernandez et al., 2015; Firth et al., 2015). Consistent with our interpretation, one service with greater socioeconomic disadvantage and symptom severity in Delgadillo et al.'s study attained a lower effect size (d=0.48) for anxiety relative to the other services (Delgadillo et al., 2016). In a larger context these findings seem to suggest health care practitioners delivering low intensity CBT need to implement more effective strategies to engage and treat these more vulnerable populations.

Study limitations include the lack of an appropriate control group to serve as a comparison to the CBTm class intervention. As Delgadillo and colleagues discuss, it is possible

symptom improvement was observed due to natural variation resulting from the passage of time, general contact with healthcare professionals, or contact with other clients (Delgadillo, Kellett, et al., 2016). Investigating the effects of large group CBT in a natural tertiary care setting is a strength as it offers an accurate estimate of the "real world" effectiveness of this intervention. This, coupled with a large sample size (*n*=523), suggests our findings likely have strong external validity. Future studies should implement a more rigorous randomized and controlled study design to clarify the effects of the intervention and minimize potential confounders. Restriction of the classes to one tertiary care clinic is also a limitation – local work is being done to expand the availability of CBTm classes across multiple sites and different settings (such as primary care) in Manitoba, Canada. Future research will stem from this initiative, offering a clearer picture of the effectiveness of large-group CBT in this region.

Conclusion

This study offers preliminary evidence supporting the acceptability and potential applicability of large group psychoeducational CBT classes in Canada. Our results demonstrate CBTm classes are a viable strategy to facilitate access and to engage and maintain clients' interest in pursuing CBT. The classes also have a modest yet statistically significant effect in treating symptoms of anxiety and depression. This study meets the national goal of providing "clinical outcomes data from a real-world setting" for CBT (Payne & Myhr, 2010), but further research needs to be done to address our study's limitations and refine our findings. As additional evidence confirms the effectiveness of these classes in Canada, they may become a key component in a client's healthcare journey as they provide psychoeducation and strategies to manage symptoms at a time when they may otherwise have difficulty accessing therapy.

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Tables

Table 1. Sociodemographic Characteristics at Intake Assessment
(n = 523)

Variable	
Age	
Years, mean (SD)	39.3 (13.8)
Sex, n (%)	
Male	178 (34.0)
Female	308 (58.9)
Unknown[†]	37 (7.1)
Marital Status, n (%)	
Married or common law	180 (34.4)
Separated, divorced, or widowed	58 (11.1)
Never married	237 (45.3)
Unknown[†]	48 (9.2)
Education, n (%)	
No high school graduation	56 (10.7)
High school graduation	117 (22.4)
Some postsecondary	107 (20.5)
Trade, college, or university certificate or diploma	47 (9.0)
University Degree	116 (22.1)
Unknown[†]	80 (15.3)
Employment, n (%)	
Paid employment or retired	251 (48.0)
Unemployed	160 (30.6)
Student	28 (5.4)
Unknown[†]	84 (16.1)
Primary mental health diagnosis, n (%)	
Anxiety Disorder[‡]	253 (48.4)
Mood Disorder[§]	214 (40.9)
Other[¶]	56 (10.7)

[†]Respondent failed to complete item. [‡]Includes GAD, SAD, panic disorder, PTSD, OCD, specific phobia, anxiety disorder NOS. [§]Includes MDD, PDD, BPD, MDE, post schizophrenic depression, postpartum depression, depression NOS. [¶]Includes alcohol and substance use disorders, eating disorders, personality disorders, somatic symptom disorders, neurodevelopmental disorders, cognitive disorders.

Table 2. Mean Changes in Outcome Measure Scores Using Mixed-Effects Linear Regression

Outcome Measure	Phase of Therapy	Mean Change¶ (95% CI)
GAD-7	Intake Assessment†	-0.98** (-1.58 to -0.38)
	CBTm Classes‡	-0.52** (-0.74 to -0.30)
	Treatment Gap§	0.79 (-0.13 to 1.71)
PHQ-9	Intake Assessment†	-0.82* (-1.51 to -0.13)
	CBTm Classes‡	-0.65** (-0.89 to -0.40)
	Treatment Gap§	1.40* (0.43 to 2.36)

†Time between intake assessment (baseline) and CBTm Class 1. ‡Effect of CBTm classes alone. Controlled for time between baseline and CBTm class 1 and treatment gap between CBTm class 4 and first small group CBT session (follow-up). §Reflects time between CBTm class 4 and follow-up. ¶For CBTm classes, reflects mean change per CBTm class attended. CBTm, Cognitive Behaviour Therapy with Mindfulness; GAD-7, Generalized Anxiety Disorder 7-item scale; PHQ-9, Patient Health Questionnaire 9-item scale. **$P \leq 0.001$. *$P \leq 0.05$.

Table 3. Mean Changes and Percent Reduction in Outcome Measure Scores between Baseline and Follow-up†

Outcome Measure	Mean Change (95% CI)	Percent Reduction, % (95% CI)
GAD-7	-2.40 (-3.38 to -1.41)	18 (9 to 24)
PHQ-9	-1.98 (-3.13 to -0.83)	13 (3 to 18)

†Intake assessment served as study baseline. First small group CBT session served as study follow-up.
GAD-7, Generalized Anxiety Disorder 7-item scale; PHQ-9, Patient Health Questionnaire 9-item scale.

Figures

Figure 1. Flow of Participants Through Outpatient Mental Health Clinic.
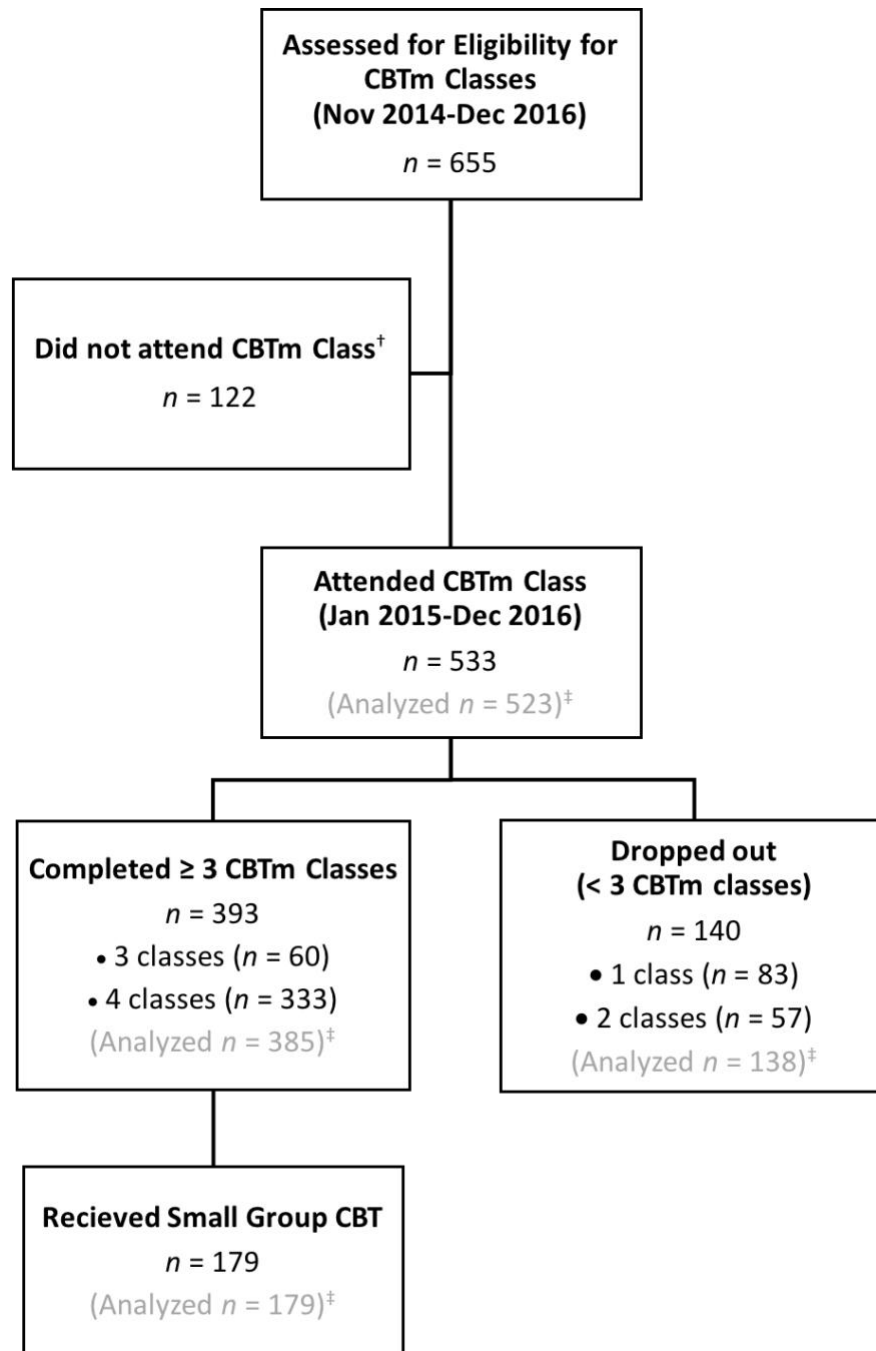
†Reasons for participants not attending include (1) meeting exclusion criteria for CBTm classes with respect to age, the presence of active psychosis or mania, acutely elevated suicide risk, or severe cognitive impairment or (2) personal reasons. ‡Participants included in data analysis had to complete at least one measure in one CBTm class from Jan 2015-Dec 2016.
CBT, Cognitive Behaviour Therapy; CBTm, Cognitive Behaviour Therapy with Mindfulness.