Acceptance and Commitment Therapy in Patients with Alcohol Use Disorder and Comorbid Treatment-Resistant Depression Who Are Undergoing Ketamine Intervention: A Feasibility Study

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1. Résumé du protocole de rechercheRaison d'être de la recherche

Les troubles liés à la consommation d'alcool (TUA), pour trouble de l'usage de l'alcool) et les troubles dépressifs coexistent fréquemment, ce qui complique la gestion clinique des patients qui en sont atteints. Pris isolément, ces deux troubles ont une prévalence importante dans la population. Lorsque les deux troubles sont comorbides, une méta-analyse récente a conclu que la coexistence pouvait atteindre 1 patient sur 5 (20,8 %). Cette comorbidité représente un défi considérable, en particulier dans les cas de dépression résistante au traitement (TRD), où les patients ne répondent pas aux interventions pharmacologiques conventionnelles.

Comme l'alcool peut agir comme un puissant déclencheur des symptômes dépressifs et, inversement, l'état dépressif augmente le risque d'abus d'alcool, la question de la séquence d'intervention est également d'intérêt clinique : faut-il donner la priorité au traitement de la TRD, de l'AUD ou des deux simultanément ? Cette question soulève un enjeu majeur pour les professionnels de la santé, car les approches thérapeutiques conventionnelles actuelles présentent des limites dans la gestion concomitante de ces troubles complexes.

Ainsi, dans certains contextes cliniques, la kétamine est apparue comme une intervention prometteuse pour traiter à la fois le TRD et le TUA. En fait, il a été démontré que la kétamine produit des effets antidépresseurs rapides mais seulement transitoire, et fait partie de l'arsenal de traitement possible pour le TRD. Le potentiel de la kétamine dans le traitement du TUA a aussi été exploré dans des études récentes, avec quelques petits essais contrôlés randomisés. Dans ces essais, l'association de la kétamine à la psychothérapie, par rapport à un placebo, a été étudiée comme moyen de soulager le TUA. Il a été démontré que la kétamine augmentait les taux d'abstinence, le délai avant la rechute et diminuait le nombre de jours de forte consommation d'alcool.

La thérapie d'acceptation et d'engagement (TAE) est une forme de thérapie cognitivo-comportementale qui met l'accent sur la flexibilité psychologique et l'acceptation des émotions et des pensées difficiles sans jugement, un type de psychothérapie particulièrement pertinent pour le TUA. Ainsi, ajouté la TAE au traitement de kétamine pourrait permettre d'augmenter la durée de l'effet de la kétamine sur les symptômes dépressifs, tout en réduisant le TUA.

Au vu de ces preuves accumulées du bénéfice potentiel de la kétamine et de la TAE, ajouter la thérapie d'acceptation et d'engagement à la kétamine apparaît comme une option prometteuse pour améliorer les résultats des patients diagnostiqués avec un TRD comorbide avec un TUA. Cette étude permettra non seulement de vérifier la faisabilité de ce type d'intervention dans cette population

particulière de patients, mais aussi les effets préliminaires sur leur consommation d'alcool et leurs symptômes dépressifs.

1.2. Objectif primaireL'adhérence des patients à l'intervention TAE sera évaluée en tant qu'objectif primaire de faisabilité.

1.3. Critère d'évaluation primaire Le nombre de patients qui terminent toutes les séances de traitement.

1.4. Critère(s) d'évaluation secondaire(s) et tertiaires En tant qu'objectif secondaire, la capacité de recrutement, le taux de recrutement, le taux de consentement, le taux d'attrition, la tolérabilité et la sécurité, le taux de collecte des données, l'utilisation des ressources et le nombre de patients s'engageant dans les exercices associés à la TAE entre les séances de thérapie seront évalués.

Pour les objectifs exploratoires, l'efficacité de l'intervention TAE combinée à la kétamine pour réduire les symptômes dépressifs et la consommation d'alcool sera vérifiée.

Pour les patients qui consentent à cette partie de l'étude, des évaluations qualitatives exploreront également la façon dont les patients souffrant de TRD et de TUA vivent la TAE assistée par la kétamine.

1.5. Devis de l'étudeÉtude de faisabilité

1.6. Population à l'étude Patients adultes (18-70 ans) souffrant de dépression résistante au traitement, unipolaire ou bipolaire, d'un trouble comorbide lié à la consommation d'alcool, et acceptés pour recevoir un traitement par kétamine IV à la clinique de kétamine par neuromodulation du CHUM.

1.7. Collecte de données : variables et mesuresRésultat primaire de faisabilité :

Adhésion du patient

Résultats secondaires de faisabilité.

Capacité de recrutement : taux de recrutement et taux de consentement

Tolérance/taux d'abandon

Nombre de patients qui assistent à au moins une séance de TAE

Nombre de semaines dans l'étude

Sécurité

Taux de collecte des données

Utilisation des ressources

Résultats secondaires d'efficacité :

Nombre de patients pratiquant les exercices de TAE entre les exercices thérapeutiques.

Résultats exploratoires

Efficacité préliminaire

L'ensemble des questionnaires listés au protocole sont administrés dans le contexte de la recherche, par le chercheur responsable ou un membre de l'équipe de recherche, et non dans le contexte de la clinique.

1.8. Conduite de l'étude et qualité des données Chaque patient participant se verra attribué un code par le personnel de recherche et ce code sera utilisé lors de la complétion des différents questionnaires à l'étude.

1.9. Taille d'échantillon Vingt participants souffrant d'une TRD modérée à sévère associée à une AUD et suivant actuellement un traitement à la kétamine seront recrutés sur une base continue.

1.10. Durée Recrutement : 12 mois

Suivi des participants : 6 mois

Durée totale de l'étude : 18 mois

1.11. Analyse statistiqueRésultats primaires : Statistiques descriptives

Résultats secondaires : Statistiques descriptives.

Résultats exploratoires : Pour évaluer l'efficacité de l'intervention, des méthodes mixtes seront employées pour analyser les scores avant et après l'intervention. L'efficacité quantitative sera évaluée sur les différents résultats continus à l'aide d'un modèle linéaire général à l'intérieur du sujet. Évaluations qualitatives : L'analyse thématique des entretiens semi-structurés sera utilisée.

Study synopsis

Full Title	Acceptance and Commitment Therapy (ACT) in patients with alcohol use disorder (AUD) and comorbid treatment-resistant depression (TRD) who are undergoing Ketamine Intervention: A Feasibility Study
Short Title	Adjunctive ACT for AUD and TRD patients receiving ketamine
Protocol and Version No.	Protocol date: 2025-10-21 Version 5.0
Principal Investigator	Dr. Nicolas Garel
Co-investigators	Dr Didier Jutras-Aswad Dr Paul Lesperance
Collaborators	Dr Paola Lavin Dr. Samuel Cyr
Funding Organizations	Fondation Famille Godin
Number of Sites	Single site: Centre de Recherche- Centre Hospitalier de L'Université de Montréal (CR-CHUM) 900 St Denis — Montréal- Canada
Study Design	This is a feasibility study that will examine the practicability, tolerability and safety of adding a psychotherapeutic intervention to patients (n=30) with alcohol use disorder (AUD) comorbid with treatment-resistant depression (TRD) who receive ketamine treatment. A comprehensive assessment will be conducted to ascertain the capability to recruit participants, analyze sample characteristics, refine measurement tools and data collection methodologies, assess attrition and determine the acceptability and appropriateness of the study's procedures.
Population	Adult (18–70 years old) patients who have treatment-resistant depression, either unipolar or bipolar, a comorbid alcohol use

	disorder, and are accepted to receive IV ketamine treatment at the CHUM neuromodulation ketamine clinic.
Primary Objectives	COMPLETION/ATTRITION and STUDY ADHERENCE ***The main feasibility outcomes*** will be evaluated by the number of patients completing all treatment sessions and by the number of participants completing all scheduled psychotherapy and ketamine infusion visits;
Secondary Objectives	*Secondary feasibility outcomes* will include the number of patients enrolled/month, the % of eligible patients who enroll in the study, the % of patients engaging in in-between ACT sessions exercises, the number of patients who attend at least one session, and the number of weeks in the study (time between the enrollment and the final assessment, or date of refusal to participate, or failure to contact). *Tolerability* will be evaluated by rates of study attrition.
Exploratory Objectives	Preliminary effectiveness outcome on depressive symptoms, alcohol use and quality of life/functioning. Ketamine-related experience will also be assessed. Absorption personality trait and working alliance between the therapist and the subject will also be verified. All the questionnaires listed will be administered in the research context, by the principal investigator or a member of the research team, and not in the clinical context.
Qualitative assessment **→ Not mandatory when participating in the feasibility study.**	Qualitative assessment to explore how patients with TRD comorbid with AUD experience ketamine-assisted ACT, based on semi-structured interviews conducted 1 to 2 weeks after their treatment is completed.

→ Based on the patient's preference at time of consent, patients will be asked if they want to participate in the semi-structured interview or not.	→ With an objective of 15 participants recruited from the 30 who took part in the main study. To achieve empirical saturation, a variability of +/- five participants is expected in the recruitment process.
Sample Size	Thirty participants with moderate to severe TRD comorbid with an AUD currently undergoing ketamine treatment will be enrolled on an ongoing basis.
Eligibility Criteria	**Inclusion criteria: patients who satisfy the following:** 1) Diagnosis of treatment-resistant unipolar or bipolar depression (TRD) (defined as the failure to respond to at least two adequate trials of psychotropics with Level 1 evidence against bipolar or unipolar depression, according to Canadian national depression guidelines) 2) Diagnosis of a comorbid Alcohol Use Disorder (AUD), assessed by a trained psychiatrist. 3) Are accepted to receive IV ketamine treatment at the CHUM neuromodulation ketamine clinic.
Intervention Arm	8 sessions of Acceptance and Commitment therapy
Control Arm	Not applicable
Study Duration	● Screening period: weeks -4 to -2 ● Baseline period: weeks -2 to 0 ● Active Intervention period: 8 weeks ● Follow up at weeks 9 to 10 (qualitative assessment, only in consenting participants), at week 12 (one month post-intervention completion) and at week 26 (six months post-intervention completion). Total duration of study participation: 8 weeks

	Total enrolment in the study: 26 weeks The study intervention comprises 8—weekly sessions of Acceptance and Commitment Therapy in patients undergoing IV ketamine treatment Assessments will take place at the baseline (week 0), weekly parallel to the ketamine intervention (weeks 3–6), at the end of the study (week 8) and at a follow-up on the weeks 12 and 26.
Outcome Measures	1. **Primary feasibility outcome:** ● **Patient adherence**: The percentage of patients completing all treatment sessions phase.
	2. **Secondary outcomes**: **<u>Secondary feasibility outcomes</u>** **2.1.- Capacity of recruitment** ● Recruitment rate (number of patients enrolled/month): This measures the number of eligible participants who are successfully enrolled in the study within a given timeframe. It provides an indication of the study's ability to attract and enroll participants. ● Consent rate (% of eligible patients enrolled): This measures the proportion of individuals approached who consent to participate in the study. A high consent rate can indicate that the study is acceptable to potential participants. **2.2.- Tolerability/Attrition rate**: This measures the proportion of participants who drop out of the study before its completion, as well as the monitoring and recording

	of any adverse events of the intervention. The frequency and severity of these reactions can provide an indication of the intervention's tolerability. The numbers of patients who attend at least one ACT session, and the number of weeks in the study (time between the enrollment and the final assessment or date of refusal to participate or failure to contact) will also be assessed. **2.3.- Safety**: This can be measured by tracking adverse events (AE) and serious adverse events (SAE) of the intervention to assess the risks associated with the intervention. Adverse effects during and after psychotherapeutic sessions will be solicited and recorded as per the Medical Dictionary for Regulatory Activities (MedDRA) Adverse Events Information at all study visits. **2.4.- E rate**: This measures the proportion of planned data that is successfully collected from participants. A high data collection rate indicates that the data collection methods are feasible and that participants are willing and able to provide the necessary data. **2.5.- Resource utilization**: This includes the cost of the intervention, the time required to deliver the intervention, and other resources used. This can help determine whether the intervention is feasible in terms of resource allocation. **<u>Secondary effectiveness outcome</u>** **2.6.- Number of patients engaging in ACT in between therapy exercises.**
	Exploratory outcomes **3.1.- Preliminary effectiveness outcomes:** To explore some effectiveness of adding ACT to ketamine infusions to change

	depressive symptom scores and alcohol use scores through different self-report questionnaires and clinician-rated scales (at the baseline, before the ketamine infusions at treatment visits, at weeks 8 weeks and 12). A trained clinician or a research assistant with at least a master's degree will complete the clinician-rated questionnaires. Absorption and working alliance between the therapist and the subject will also be assessed. All the questionnaires listed will be administered in the research context, by the principal investigator or a member of the research team, and not in the clinical context. In response to the insights garnered from this feasibility study, strategic amendments will be made to the research protocol. Subsequently, a methodologically rigorous, randomized, and controlled trial will be initiated.
	Qualitative assessment: In patients who completed at least 3 ACT sessions and 1 ketamine infusion, semi-structured interviews will be conducted 2 weeks after completion of treatment to explore qualitatively how patients with TRD comorbid with AUD experience ketamine-assisted ACT.
Participant Safety	AE and SAE throughout the study will be recorded by the clinical and research team and reported in a timely manner. AEs during and the psychotherapy sessions will be solicited and recorded as per the Medical Dictionary for Regulatory Activities Adverse Events Information at all study visits.
Statistical Analysis	**Primary outcomes:** Descriptive statistics **Secondary outcomes:** Descriptive statistics.

	Exploratory outcomes: To evaluate the intervention's effectiveness, mixed methods will be employed to analyze pre- and post-intervention scores. Quantitative efficacy will be assessed on the different continuous outcomes using within subject general linear model. **Qualitative assessments:** Thematic analysis through semi-structured interviews will be used.
Potential Implications	The adjunction of ACT to an ongoing ketamine treatment could offer a novel approach to managing TRD comorbid with AUD, potentially providing sustained relief for patients unresponsive to conventional treatments. The findings may guide future clinical practices in the combined use of psychotherapy and pharmacotherapy for TRD and AUD, with potential global implications for mental health services.

2. Introduction

2.1. Raison d'être de la recherche *(Study rationale)*

Acceptance and Commitment Therapy (ACT) has been proposed as a particularly well-suited form of psychotherapy to be added to ketamine for improving its rapid but short antidepressant action (1-4). This is in part because of ketamine's acute effect on psychological flexibility (5, 6), a crucial construct that is addressed with ACT.

There has been extensive efforts to find effective strategies to enhance and sustain the therapeutic response of ketamine, with most attempts using various pharmacotherapies—such as clonidine, D-cycloserine, lamotrigine, lithium, rapamycin, and riluzole— which have yielded mostly disappointing results (7, 8). Consequently, the most common approach to extending ketamine benefits has been to administer repeated doses, although there is limited evidence supporting the long-term safety, efficacy, and practicality of this practice (9, 10).

Substantial evidence indicates that psychotherapy can enhance the effects of pharmacological treatments, such as oral antidepressants, and even help maintain their benefits after discontinuation (11-13). While further research is required, it is plausible to assume that similar benefits of adding psychotherapy could extend to ketamine, particularly considering its potential neuroplastic effects (14).
In view of the accumulated evidence, the addition of ACT to a ketamine intervention appears as a promising option to improve the outcomes of patients diagnosed with AUD comorbid with TRD. This study will not only verify the feasibility of adding psychotherapy to ketamine in this population, but also the effect on their alcohol consumption and depressive symptoms.

2.2. Recension des écrits *(Background)*<u>Background</u>

Alcohol Use Disorder (AUD) and depressive disorders frequently coexist and complicate the clinical management and treatment outcomes for patients. It is estimated that around 1 in 10 people (10.4%) in the USA is experiencing a major depressive disorder (MDD) in the course of a year, while it goes up to 1 in 5 (20.6%) in the course of a lifetime (15). As for AUD, twelve month and lifetime prevalence are respectively 13.9% and 29.1% (16). When these disorders coexist, the prevalence is estimated as high as 20.8%, as reported by a recent meta-analysis(17). Research has also shown that individuals with AUD are approximately 2.3 times more likely to experience MDD within a given year (18).

This comorbidity presents a formidable challenge, particularly in cases of Treatment-Resistant Depression (TRD), a subset of MDD where patients do not respond to conventional pharmacological interventions. In the United States, it is estimated that out of 8.9 million adults receiving medication for MDD, 2.8 million, or 30.9%, are grappling with TRD (19). The economic impact is substantial, with the total

annual cost of medication-treated MDD reaching $92.7 billion, nearly half of which—$43.8 billion or 47.2%—is attributable to TRD (20).

The concomitance of TRD and AUD represents a major clinical challenge (21) as alcohol can act as a powerful trigger for depressive symptoms, and conversely a depressive state can increase the risk of alcohol abuse. This creates a complex, bidirectional relationship between the two disorders, considerably complicating the assessment and clinical management of these concurrent disorders (22, 23). The question of intervention sequence is also of clinical interest: should treatment of TRD, AUD, or both simultaneously be prioritized? This question raises major challenges for health professionals, as current conventional therapeutic approaches present limitations in the concomitant management of these complex disorders (21, 24). Traditional pharmacological treatments, such as antidepressants, may not be sufficiently effective or tolerated by some patients to treat these comorbid disorders (25). As for standard psychotherapeutic approaches, such as cognitive-behavioral therapy, the heterogeneity of symptoms and diversity of issues often mean that the needs of individuals suffering from these comorbidities cannot be met comprehensively (25).

In response to this challenge, in selected clinical settings, ketamine has emerged as a promising intervention for treating AUD and depressive disorders. Ketamine, an NMDA receptor antagonist, has been shown to produce rapid and substantial, albeit short-lived (i.e., 7 days), antidepressant effects in individuals with TRD (26-28). Furthermore, ketamine's potential in treating AUD has been explored in recent studies, with various methodologies, including randomized controlled trials (29, 30). In 2022, Dr. Garel, principal investigator of this project, published a systematic review of the literature on the use of ketamine in adults with problematic alcohol use or alcohol use disorder (31). Eight studies were included, and 1 involved patients with a depressive comorbidity. Ketamine, administered with or without concurrent psychotherapy, demonstrated promising results. Since the publication of this systematic review, our team is aware of three further randomized controlled trials on the subject, published in 2022 (32) and 2024 (33, 34). Altogether, a total of 12 articles have been published with the use of ketamine in patients with alcohol use disorder.

Looking at a similar population to this project (i.e., patients with a comorbidity of depression and AUD), Yoon et al. performed a small (n=5), unblinded and uncontrolled study, of patients with a diagnosis of both depression and AUD. In their study, the combination of naltrexone (an FDA-approved drug for AUD) and ketamine reduced both depressive symptoms and alcohol craving. Indeed, 60% of patients met the response criteria for depressive symptoms reduction after their initial ketamine dose, while 100% met those criteria by their fourth dose, and 80% of patients reported an improvement in alcohol craving and

consumption (35). Naturally, the design of this study and its small sample size make it difficult to draw definitive conclusions about the efficacy of ketamine in this population, and further studies are therefore needed. One other team also studied the use of ketamine in patients with both depression and AUD, but their primary objective, rather than alcohol outcomes, was whether having a diagnosis of AUD impacted the antidepressant effect of ketamine in people with severe major depressive disorder or bipolar depression (33). The study showed that the ketamine's antidepressant effects were not impacted by a concurrent AUD. Furthermore, a statistical trend toward a superior improvement in suicidality was observed in participants with comorbid AUD.

The use of ketamine in patients with AUD was studied in five randomized controlled trials that have been conducted since the 1990s. The team of Krupisky et al. studied 186 treatment-seeking alcohol-dependent patients who had failed to maintain sobriety during a three-month follow-up in the outpatient department. They studied ketamine therapy in addition to treatment as usual Vs. treatment as usual alone (36), and found a significant difference between the groups for abstinence at one year. In more contemporary studies (>2019), other teams also compared the use of ketamine-assisted psychotherapy with placebo-assisted psychotherapy to assess different AUD outcomes, including abstinence and craving. In 2019, Das et al. studied 90 volunteers with hazardous/harmful drinking habits, and used ketamine in a combined ketamine-behavioural intervention context (29). Using self-reported Likert scales for cue- and not cue-induced urges to drink (i.e., craving), they found a significant reduction in the ketamine group compared to control. In 2020, Dakwar et al. (as well as Rothberg et al. in a secondary analysis) further investigated 40 treatment-seeking alcohol-dependent patients with AUD (30, 37). Patients were randomized to receive either a ketamine infusion and motivational therapy or an infusion of an active placebo (i.e., midazolam) and the same therapeutic intervention. It was found that the patients in the ketamine group had improved rates of abstinence, prolonged time to relapse, and fewer days of heavy drinking than individuals in the control group. Grabski et al., in 2022, compared the use of ketamine with a relapse prevention-based psychological therapy to placebo and found that there was a significant increase in the number of days abstinent from alcohol (32). Finally, a double-blind pilot study assessed sublingual esketamine combined with a mindfulness-based intervention (MBI) in 28 participants. Results showed that esketamine enhanced psychological engagement with MBI, temporarily reduced alcohol cravings, and increased mystical experiences, suggesting its potential to optimize mindfulness-based therapies (34).

It's also worth noting that, beyond the randomized controlled studies available, experts are increasingly presenting psychedelics (including ketamine) as a potential solution for the treatment of

comorbid depression and AUD. For example, de Jonge et al. recently presented an article on the pressing need for research into psychedelics precisely for the treatment of this comorbidity (38). Our project therefore ties in with the unmet need in this field.

Considering the substantial but transient effect of ketamine on depressive symptomatology, and its promising results in AUD patients, a novel approach is to add a psychotherapeutic component to the ketamine treatment with the aim of enhancing and prolonging its effect. Acceptance and Commitment Therapy (ACT) seems to be a particularly well-suited form of psychotherapy to be added to ketamine treatment (4). Indeed, ACT is a form of cognitive-behavioural therapy that emphasizes psychological flexibility and the acceptance of difficult emotions and thoughts without judgment. ACT has been extensively studied in various psychopathologies, including anxiety and depression, demonstrating positive outcomes in multiple rigorous clinical trials and meta-analysis. Growing evidence suggest that ACT may be an effective and even superior treatment for individuals with substance use disorders (39) ACT encourages individuals to commit to behavior changes consistent with their values, which can be particularly beneficial for those with AUD and comorbid TRD (40, 41). Ketamine has been shown to have an acute effect on psychological flexibility (5, 6), and the addition of ACT's focus on acceptance and value-driven behavior holds promise for improving the ketamine's rapid and short antidepressant action and addressing the complex interplay of AUD and TRD.

Standard treatment options

Alcohol Use Disorder (AUD):

In 2023, a committee of AUD specialists published the Canadian guideline with treatment recommendations for AUD (42). As a strong recommendation, they first proposed that all patients with AUD should be offered specialist-led psychosocial treatment interventions, such as cognitive behavioral therapy or family-based therapy. However, both therapies were found to have small to medium beneficial impacts on AUD outcomes (43, 44). For pharmacotherapy, as a complement to the psychosocial treatment, naltrexone or acamprosate were recommended as first-line therapy. Second-line options, some of them being used as off-label therapies, were also proposed, namely gabapentin, topiramate and disulfiram. Of note, these recommendations are in line with other reviews of AUD pharmacotherapy (45-48) and other national guidelines (namely American and Australian guidelines).

However, there are some limitations associated with the use of those treatment options. Apart from safety concerns, with common AE associated with treatments (nausea, dizziness and fatigue, among others), there is an ongoing debate among experts about the actual efficacy of the treatment options. In fact, naltrexone and acamprosate have an estimated number needed to treat to prevent a return to heavy

drinking of 12 (49), with modest differences found when comparing drugs with placebo. (36) contributing to their underutilization in AUD patients. For instance, in over 28,000 Medicare beneficiaries hospitalized with a primary or secondary diagnosis of AUD, it was found that only 0.7% of patients started pharmacotherapy within two days after discharge and 1.3% within 30 days (37). Even among patients for whom AUD was the primary diagnosis after hospitalization, only 2.3% started pharmacotherapy within two days of discharge (50).

Treatment Resistant Depression (TRD):

Leading experts in TRD summarized in 2023 the options available to try and reach a favorable outcome in individuals who fail to respond to at least two adequate trials of psychotropics against depression (51). First, extending a current antidepressant trial could be a potential treatment plan. A systematic review determined that up to 20% of patients who did not respond to their antidepressant in the first four weeks of treatment responded during the following four weeks (from weeks five to eight), and up to 10% during weeks nine to twelve (52). Similarly, there is some evidence, albeit conflicting (53), that switching antidepressants or combining antidepressants could benefit some patients, especially if the change or addition involves a new mechanism of action (54). To cite only one example of this option, adding antidepressants with antagonism activity on the alpha-2 receptor (i.e., mirtazapine, trazodone) to a selective serotonin reuptake inhibitor was superior to monotherapy in a meta-analysis (55).

Other treatment modalities have also been studied, including adding various pharmacological agents like second-generation antipsychotics and mood stabilizers. In real-world settings, most patients with TRD are prescribed multiple psychotropic medications, often for extended periods, with generally limited success (56). For example, a recent cohort study conducted over 12 months across various European countries, involving 411 patients with TRD, highlighted high rates of polypharmacy alongside modest clinical improvement—only about 30% showed a positive response after 6 to 12 months of consistent treatment (57). The study also indicated a concerning level of therapeutic inertia, where 60% of patients did not undergo any changes in their treatment plan, despite ongoing poor outcomes (44).

Electroconvulsive therapy (ECT), aside from the usual pharmacological approaches, is considered one of the most empirically supported interventions for TRD (58, 59). However, despite its effectiveness, ECT is often hindered by significant barriers, including societal stigma, inconsistent access, and notable side effects such as memory loss, largely due to the need for general anesthesia during the procedure (60-62).

Amid the current treatment challenges, the rapid and robust antidepressant effects of subanesthetic doses of IV racemic ketamine—a distinctive N-methyl-D-aspartate (NMDA) receptor

antagonist—have sparked considerable interest and optimism. Meta-analyses suggest that nearly half of patients with treatment-resistant depression (TRD) experience a significant reduction in depressive symptoms (over 50%) within just hours to days following a single 40-minute IV ketamine infusion (26-28). This promising efficacy has led many experts to regard subanesthetic ketamine as one of the most transformative advancements in psychiatric pharmacology in recent decades (63). While impressive, ketamine's benefits typically fade within days or weeks

Given the evidence of ketamine's beneficial effect, the neuromodulation service of the CHUM, directed by Dr Paul Lespérance, began providing this treatment to patients with TRD in 2018, covering the whole province of Quebec. Since then, the neuromodulation service has created a state-of-the-art infrastructure for the ketamine service.

2.3. Bénéfices et risques *(Benefits and risks)* Overview of adverse events that can occur during a psychological intervention. It is expected that ACT intervention will have very few side effects. A recent systematic study showed that around 1 in 20 patients (5%) experience AEs of psychotherapy (e.g., deterioration of symptoms, appearance of new symptoms or dependence on therapist treatment) and 1 in 40 (2.5%) experience SAEs (e.g., self-harm or suicide attempts) (64, 65). There is also an infrequent possibility (less than 1%) of AE occurring during incorrectly applied treatment, such as malpractice (for example feeling insulted by statements of the therapist, feeling of not being taken seriously or mocked) or unethical conduct (for example breach of confidentiality) (64-66).

3. Objectifs et critères d'évaluation *(Objectives and endpoints)*

3.1. Objectif primaire *(Primary objective)* As a primary feasibility outcome, the patient adherence to the ACT intervention (i.e., the percentage of patients enrolled completing all treatment sessions) will be assessed.

3.2. Objectif(s) secondaire(s) *(Secondary objectives)* As secondary feasibility outcomes, the capacity of recruitment will be assessed with the recruitment rate (number of patients enrolled/month) and the consent rate (% of eligible patients enrolled). Also, for tolerability and attrition rate, the proportion of participants who drop out of the study before its completion, as well as the monitoring and recording of any AE of the intervention will be verified (65). The numbers of patients who attend at least one ACT session, and the number of weeks in the study

(time between the enrollment and the final assessment or date of refusal to participate or failure to contact) will also be assessed (67, 68).

Finally, the data collection rate (% of planned data that is successfully collected from participants), and the resource utilization (cost of the intervention, time required to deliver the intervention, and other resources used) will also be secondary feasibility outcomes.

As a secondary effectiveness outcome, the number of patients engaging in ACT in between therapy exercises will be assessed.

3.3. Objectif(s) tertiaire(s) /exploratoire(s) *(Tertiary / exploratory objectives)*

The effectiveness of the ACT intervention combined with ketamine to decrease depressive symptoms and alcohol use through different self-report questionnaires and clinician-rated scale (at baseline, before the infusions at treatment visits, at weeks 8, 12 and 26) will be verified as an exploratory outcome.

Absorption and working alliance between the therapist and the subject will also be assessed.

All the questionnaires listed will be administered in the research context, by the principal investigator or a member of the research team, and not in the clinical context.

Exploratory outcomes

Summary	
Alcohol-related outcomes	
Alcohol Use Disorder Remission of AUD: According to DSM-5 criteria: "Early remission indicates a period ≥3 months but <12 months without meeting DSM-5 substance use disorders criteria other than craving." Three months' duration was selected because data indicated better outcomes for those retained in treatment at least this long.	Alcohol Use Disorders Identification Test (AUDIT) - 10 items (69-74) *Delivery method:* Self-administered AUDIT was first developed as a screening questionnaire for hazardous and harmful alcohol consumption. Across its 10 items, three main domains are verified, namely hazardous alcohol use, dependence symptoms, and the harmful alcohol use. Over the years, its use has been extended from screening to a wider context, including in clinical care research, and its validity has been proven repeatedly, in several different studies (74). Interestingly, well-established risk thresholds (low-risk consumption, hazardous or harmful alcohol consumption, and alcohol dependence (moderate-severe alcohol use disorder) have already been identified. Internal reliability (Cronbach's alphas were ≥ 0.80 in many studies) (75) Assessments at weeks 0, 8, 12, and 26
Alcohol use	Timeline Followback (TLFB) (78, 79)

● Frequency ● Quantity—Number of drinks per drinking day ● % Heavy drinking days ○ For women: 4 or more drinks on any day ○ For men: 5 or more drinks on any day ● % Alcohol dose reduction ● Alcohol cessation rate ● % Abstinent day ● Reductions in drinking risk level (WHO) (76, 77)	*Delivery method:* Clinician-administered With the TLFB method, clinical/study personnel provide calendar-based memory cues to help patients build up chronological reports of their alcohol use within an established period. It is considered the gold-standard method to assess alcohol use/quantity (80). Assessments at weeks 0, 1, 2, 3, 4, 5, 6, 7, 8, 12, and 26
Craving	<u>Alcohol Craving Questionnaire (ACQ-NOW) - 47 items (81, 82)</u> *Delivery method:* Self-administered

	The ACQ scale allows for the assessment of craving associated with alcohol, with (1) the desire to drink alcohol, (2) the intention to drink alcohol, (3) the lack of control over the use of alcohol, (4) the anticipation of positive effects from drinking, and (5) the expectancy of relief from withdrawal or alcohol's negative effects. These five elements then connect to four different dimensions, namely compulsivity, expectancy, purposefulness and emotionality. Internal reliability (Cronbach's alpha = 0.94) (83) Assessments at weeks 0, 8, 12, and 26 <u>Obsessive-Compulsive Drinking Scale (OCDS) - 14 items (84, 85)</u> *Delivery method:* Self-administered The OCDS measures an individual's alcohol use as well as the attempts to control the drinking, with an obsessive and a compulsive subscale. Internal reliability (Cronbach's alpha = 0.86) Assessments at weeks 0, 1, 2, 3, 4, 5, 6, 7, 8, 12, and 26
Motivation	<u>Stages of Change Readiness and Treatment Eagerness Scale (SOCRATES) - 19 items (86)</u>

	Delivery method: Self-administered The SOCRATES scale assesses the subject's readiness to change and to enter alcohol disorder related treatment, with three main factors being verified (recognition, ambivalence, and taking steps). Internal reliability (Cronbach's alpha = 0.60 to 0.96) Assessments at weeks 0, 8, 12, and 26
Self-efficacy	<u>Alcohol Abstinence Self-Efficacy Scale (AASE) - 12 items (87, 88)</u> *Delivery method:* Self-administered AASE was developed to assess the individual's self-confidence about his ability to avoid drinking in a given situation. Internal reliability (Cronbach's alpha = 0.88) Assessments at weeks 0, 8, 12, and 26
<u>Mental health-related outcomes</u>	
Depression	<u>Montgomery-Asberg depression rating scale (MADRS) - 10 items (89, 90)</u>

	Delivery method: Clinician-administered MADRS is a clinician-administered scale that evaluates the severity of depression. Each item, which ranges from apparent sadness to reported sadness, inner tension, reduced sleep, reduced appetite, concentration difficulties, lassitude, inability to feel, pessimistic thoughts and suicidal thoughts, is rated on a 7-point scale, as decided by the clinician rater. This scale is widely used in depression studies because of its great sensitivity to change over time. Internal reliability (Cronbach's alpha = 0.76) (91) Assessments at weeks 0, 1, 2, 3, 4, 5, 6, 7, 8, 12, and 26 <u>Beck Depression Inventory-II (BDI–2) - 21 items (92)</u> *Delivery method:* Self-administered This scale was specifically designed to assess the severity of depression symptomatology, with well-validated cut-off for minimal, mild, moderate and severe depression. Internal reliability (Cronbach's alpha = between 0.85 and 0.88) (91) Assessments at weeks 0, 1, 2, 3, 4, 5, 6, 7, 8, 12, and 26
Anxiety	<u>General Anxiety Disorder (GAD7) - 7 items (93)</u>

	Delivery method: Self-administered GAD7 allows for the identification of probable cases of generalized anxiety disorder (GAD) as well as assessing the symptom severity. Internal reliability (Cronbach's alpha = 0.92) Assessments at weeks 0, 1, 2, 3, 4, 5, 6, 7, 8, 12, and 26
Suicide Ideation	<u>Beck Scale for Suicide Ideation (BSS) - 19 items (94)</u> *Delivery method:* Trained staff or Self-administered The BSS measures attitudes and behaviours associated with suicide risk and allows the disclosure of specific suicidal characteristics. Internal reliability (Cronbach's alpha=0.89) Assessments at weeks 0, 1, 2, 3, 4, 5, 6, 7, 8, 12, and 26.
<u>Ketamine experience-related outcomes</u>	
Mystical Experience	<u>Mystical Experience Questionnaire (MEQ) - 30 items (95-97)</u> *Delivery method:* Self-administered

	The MEQ verifies the mystical experience associated with psychedelics-assisted psychotherapy, under a 4-factor structure. The factors cover (1) sacredness, (2) positive mood, (3) transcendence of time and space, and (4) ineffability. Internal reliability (Cronbach's alpha = 0.93) Assessments at weeks 3, 4, 5, and 6
Emotional Breakthrough	<u>Emotional Breakthrough Inventory (EBI) - 6 items (98)</u> *Delivery method:* Self-administered EBI assesses the experience of emotional release or breakthrough during psychedelics-assisted psychotherapy. Roseman et al. compared emotional breakthrough to the notion of catharsis, or the healthy release of an emotion that was buried or not adequately addressed (ref: Jackson, 1994) Internal reliability (Cronbach's alpha = 0.93) Assessments at weeks 3, 4, 5, and 6
Mindfulness	<u>Five Facet Mindfulness Questionnaire (FFMQ) - 39 items (99)</u>

	Delivery method: Self-administered Mindfulness is described by the American Psychological Association as the awareness of one's internal states and surroundings (100). The FFMQ assesses across 39 items five facets of a person's tendency to be mindful in its daily life ([1] observing, noticing, and attending to sensations, perceptions, thoughts, and feelings; [2] describing/labelling one's experience; [3)] acting with awareness; [4] non-judging; and [5] non-reactivity to inner experience. Internal reliability (Cronbach's alpha ≥ 0.82) (101) Assessments at weeks 0, 8, 12 and 26
<u>Psychotherapy-related outcomes</u>	
Absorption	<u>Modified tellegen absorption scale (MODTAS) (102)</u> *Delivery method:* Self-administered The MODTAS consists of 34 items assessing the absorption personality traits. Absorption involves an openness to experience emotional and cognitive alterations across a variety of situations (103), and is associated with psychotherapy success (104). Internal reliability (Cronbach's alpha = 0.96) (105)

	Assessments at weeks 0
Working Alliance	<u>Working Alliance Inventory for patients (WAI-SR) (106)</u> *Delivery method:* Self-administered The WAI-SR consists of 12 items assessing the working alliance between the therapist and the subject, and it is associated with psychotherapy success (106). Internal reliability (Cronbach's alpha > 0.70) (107) Assessments at weeks 1, 2, 3, 4, 5, 6, 7, and 8 <u>Working Alliance Inventory for therapist (WAI-SRT) (106)</u> *Delivery method:* By the therapist; Self-administered The WAI-SRT consists of 10 items assessing the working alliance between the therapist and the subject, and it is associated with psychotherapy success (106). Internal reliability (Cronbach's alpha > 0.70) (107) Assessments at weeks 1, 2, 3, 4, 5, 6, 7, and 8

Quality of life/functioning	
Quality of life	EQ-5D-5L— 5 items + visual analog scale (108, 109) *Delivery method:* Self-administered The 5-level EQ-5D version consists of 2 parts: the EQ-5D with 5 items pertaining to quality of life and the EQ visual analogue scale (EQ VAS). The descriptive system comprises five items about mobility, self-care, usual activities, pain/discomfort and anxiety/depression, and each item has 5 levels, from no problems, slight problems, moderate problems, severe problems to extreme problems. The EQ VAS looks at the patient's self-rated health on a vertical visual analogue scale where the endpoints are labelled "The best health you can image" and "The worst health you can image." Internal reliability (Cronbach's alpha=0.90) (110) Assessments at weeks 0, 8, 12, and 26
Functioning/disability	WHO Disability Assessment Schedule (WHODAS 2.0) - 12 items (111, 112) *Delivery method:* Self-administered WHODAS 2.0 is an instrument for measuring functioning and disability, widely used in clinical research and in the general population. It verifies the level of functioning in 6 domains, namely cognitive, mobility, personal care, relationships with others, daily activities and social participation.

	The 12-item scale (a short form from the 36-item version) is useful for brief assessments of overall functioning and still allows computing overall functioning scores. Also, the 12-item short version of the WHODAS 2.0 explained 81% of the variance of the 36-item version. Internal reliability (Cronbach's alpha=0.90) Assessments at weeks 0, 8, 12, and 26

Qualitative descriptive research is considered appropriate for providing a comprehensive, detailed and complete description of phenomena as experienced and perceived by participants (113), by analyzing several individual cases, revealing the variability of treatment experiences while identifying cross-cutting trends and themes.

For patients who completed at least 3 ACT sessions and 1 ketamine infusion, and provide additional verbal consent, a semi-structured qualitative interview will be offered with the purpose of exploring how patients with TRD comorbid with AUD experience ketamine-assisted ACT. This will allow us to collect data on individual experiences of ACT and better understand the therapeutic mechanisms underlying the experience of ketamine-assisted ACT from the perspective of patients.

Interviews will be voice recorded for transcription purposes. As soon as the transcriptions are completed, the recordings will be immediately destroyed. Transcripts will be anonymized, and securely and confidentially stored.

As for data analysis, the three researchers in charge of the analysis will first familiarize themselves individually with the data, by reading the transcribed interview. Then, together, they will read the verbatim in depth to identify recurrences and units of meaning and define the first themes. These will be illustrated with examples taken from the interviews. Following this, two researchers will share the first and second parts of the initial coding of the verbatim, while the third will examine their potential themes for validation purposes. The researchers then meet to pool and discuss the themes collectively. These are revised and refined as necessary to ensure that each theme is well supported by the data collected. This procedure is repeated until saturation in two consecutive verbatim analyses.

Qualitative assessment

Qualitative assessment	Semi-structured interview The interview is scheduled to take place two weeks after the end of their treatment, on the premises of the CHUM psychiatry department or in a virtual setting, depending on the preference of the patients. Each interview will last approximately one hour to 90 minutes, allowing for an in-depth exploration of the various dimensions of the ketamine-assisted psychotherapy experience. The interview will take place face-to-face in a confidential and comfortable setting, to ensure an environment conducive to the free expression of participants. An interview guide was conceptualized following the appropriation of the literature on ketamine in psychiatry, in relation to the various concepts under study, as well as the wider literature on psychedelic-assisted therapies (114). Interviews will be recorded for transcription purposes. As soon as the transcriptions are completed, the recordings will be immediately destroyed. Transcripts will be anonymized, and securely and confidentially stored. Assessments at week 10

3.4. Critère d'évaluation primaire *(Primary endpoint, primary outcome measure)* Patient adherence

3.5. Critère(s) d'évaluation secondaire(s), tertiaire(s) / exploratoire(s) *(Secondary, tertiary / exploratory endpoints)* Secondary endpoints:

Capacity of recruitment: Recruitment rate and consent rate

Tolerability/Attrition rate

Safety

Data collection rate

Resource utilization

Number of patients engaging in ACT exercises in between therapy exercises.

Exploratory endpoints:

Alcohol-related

- Alcohol Use Disorder
  - Remission of AUD
- Alcohol use
  - Frequency
  - Quantity—Number of drinks per drinking day
  - % Heavy drinking days
  - % Alcohol dose reduction
  - Alcohol cessation rate
  - % Abstinent day
  - Reductions in drinking risk level [WHO]
  - Craving
  - Motivation
  - Self-efficacy

Mental health-related

- Depressive symptoms
- Anxiety
- Suicide Ideation

Ketamine experience-related

Mystical Experience

Emotional Breakthrough

Mindfulness

Quality of life/functioning

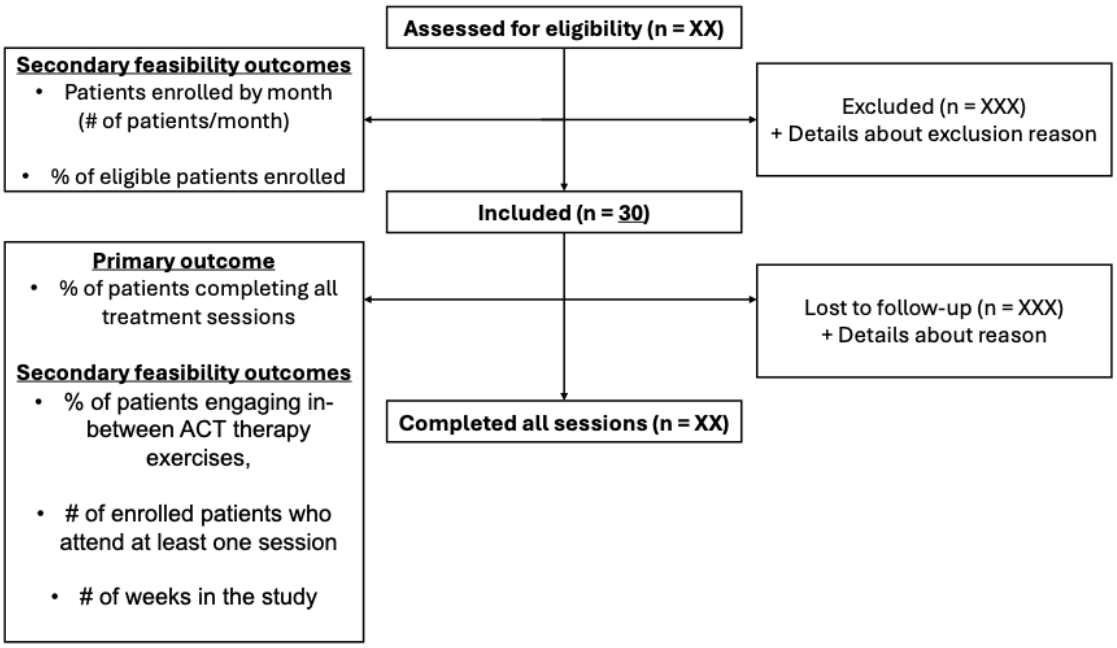
Quality of life

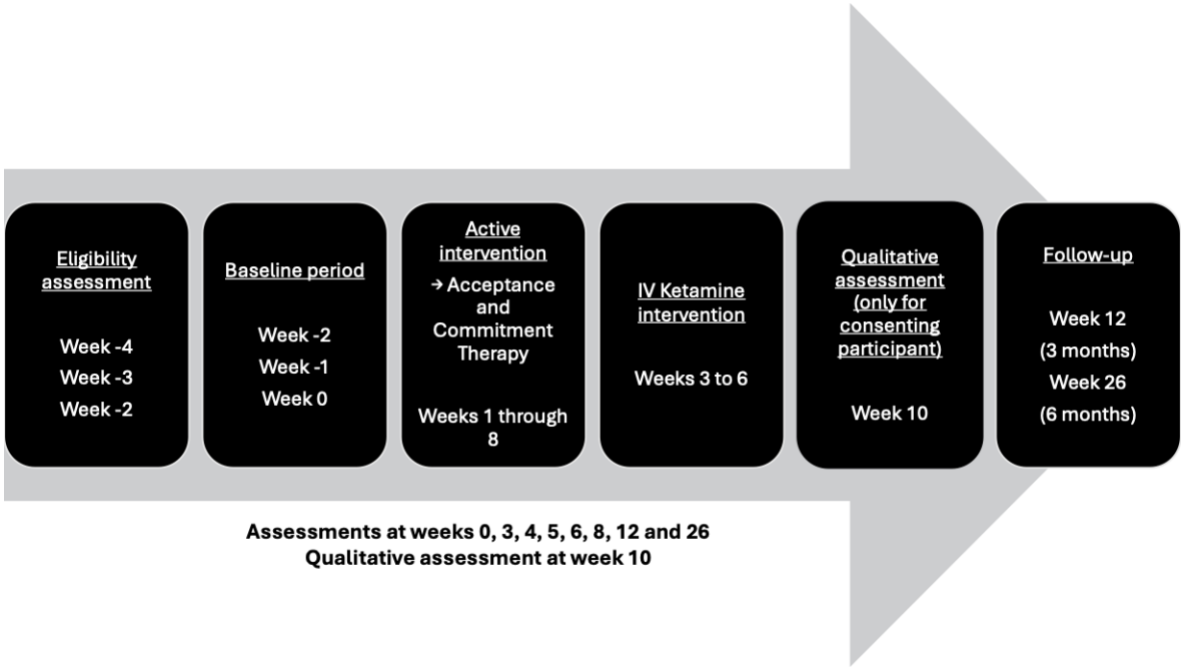
Functioning/disability

4. Méthodes *(Methods)*

4.1. Devis et contexte de l'étude *(Study design and context)* This is a feasibility study that will examine the practicability, tolerability and safety of a psychotherapeutic intervention to patients (n=30) with alcohol use disorder (AUD) comorbid with treatment-resistant depression (TRD) who receive ketamine treatment. A comprehensive assessment will be conducted to ascertain the capability to recruit participants, analyze the characteristics of the resultant sample, refine measurement tools and data collection methodologies, assess attrition and determine the acceptability and appropriateness of the study's procedures. Additionally, an evaluation of the resources required for the study will be systematically performed.

For exploratory outcomes, preliminary effectiveness of the intervention, with alcohol-related, experience-related, mental health-related and quality of life/functioning outcomes will be assessed. Also, a qualitative interview, conducted two weeks after the end of their treatment will be conducted to explore the patients' experience with ketamine-assisted ACT.





Assessments at weeks 0, 3, 4, 5, 6, 8, 12 and 26
Qualitative assessment at week 10

4.2. Population à l'étude *(Study population)* Adult (18–70 years old) patients who have treatment-resistant depression, either unipolar or bipolar, a comorbid alcohol use disorder, and are accepted to receive IV ketamine treatment at the CHUM neuromodulation ketamine clinic.

4.2.1. Critères d'inclusion *(Inclusion criteria)*

Patients who satisfy the following inclusion and exclusion criteria of the study will be invited to enroll:

- Have a diagnosis of treatment-resistant unipolar or bipolar depressive episode, with a current episode of depression (DSM-5) despite at least two adequate trials of psychotropics with Level 1 evidence against bipolar and unipolar depression (115, 116) as per the Montgomery-Asberg Depression Rating Scale (MADRS) ≥ 20 (89, 90);
- Have a comorbid alcohol Use Disorder (AUD) as diagnosed by a trained psychiatrist, with an average daily ethanol consumption of at least a moderate risk according to the WHO risk level (Men: >40 to 60 g/day or >2.9 to 4.3 drinks/Women:>20 to 40 g/day or>1.4 to 2.9 drinks) (76, 77);
- Have been accepted for treatment by IV ketamine for depression and AUD;
- Provision of written informed consent after reading the patient information handout;
- Desire to engage in 8 weekly psychotherapy sessions;
- No changes to medications during treatment;
- Age> 18-70 years old;

4.2.2. Critères d'exclusion *(Exclusion criteria)*

Participants will be excluded if any of the following criteria are met:

- currently participating in other evidence-based psychotherapeutic intervention for mood disorders or substance abuse
- Is not able to commit to the study protocol secondary to professional/personal obligations
- Is non-English or non-French speaking.
- Any psychiatric comorbidity that is severe, unstable, or likely to take precedence over AUD/TRD in terms of clinical management.
- Acute psychotic disorder and acute psychotic symptoms, as judged by the initial clinical interview or reported by referring clinician.
- Any neurocognitive decline impacting the capacity to engage in psychotherapy, as assessed by the participants' clinicians and/or PI.

- One year prior or current substance abuse or dependence other than AUD, caffeine, nicotine, or cannabis dependence), as defined by DSM-5 criteria
    - In the context of its legalization, recreational use that does not meet criteria for a substance use disorder and/or is not deemed to be negatively impacting patients' physical and mental health will not justify the exclusion from the study just as it does not justify the exclusion from purely clinical treatment by ketamine

4.2.3. Sélection ou recrutement des participants (*Participant selection or recruitment*)For potential participant recruitment, patients suffering from treatment-resistant depression comorbid with alcohol use disorder and accepted for ketamine treatment will be identified by physicians of the neuromodulation clinic. Physicians will ask participants for verbal consent to be contacted by the research team. If the patient consents, the physician will then transfer the patient's information to the research team, who will then contact the patient to begin the research process. It will be emphasized, before and during the consenting procedure, that the acceptance or refusal to participate in this study will not in any way influence the relationship with the Ketamine clinic team or the ketamine treatment.

Number of Sites

There will be one clinical site participating in the trial, the CHUM neuromodulation ketamine service. The enrollment target for this study is 30 participants.

Site Characteristics

The site participating in this trial demonstrated willingness and capacity to:

1. Provide type of treatment: 8 sessions of Acceptance and Commitment Therapy in 2 modalities to be selected by the patient's preference before the start of the intervention (online or in-person).
2. Agree to offer this type of intervention: Chloé Radziszewski, a social worker currently completing hours to be formally accredited by her professional organization to perform psychotherapy. She is completing those hours at the CHUM's Addiction Psychiatry Clinic, and is already seeing patients. She will be trained in ACT therapy along with the other members of the therapy team. Serge Drolet, Leaticia Alexe and Nicolas Gamin, three experienced licensed psychologist, will also provide the psychotherapy.

3. Have a sufficient patient population to achieve study enrolment targets: currently, the CHUM's ketamine clinic is one of the major centres in Canada who receive patients for ketamine treatments.
4. Have sufficient psychiatrist availability and acceptance of the study to refer patients and adhere to protocol: Dr. Paul Lesperance, Dr. André Do, and Dr. Francois Trottier-Duclos, all working in the ketamine neuromodulation clinic have welcomed the proposal to submit the present study for review and extended their unequivocal support to our research team.

4.3. Collecte de données : variables et mesures *(Data collection : variables and measurements)*

4.3.1. Procédures et déroulement de l'étude *(Study procedures and execution)* Initial contact with the patient will be made by telephone by the research team (see below for telephone script). If the participant is interested in participating in the study, he/she will be offered several time slots in the morning, afternoon, or early evening. Next, a meeting will be scheduled with the patient via Teams. At this time, the consent form will be sent to the participant so that he/she can read it once before meeting the research assistant. In the TEAMS meeting, which will be recorded, the project will be explained to the patient, and the research team member will go through the IFC. The patient will then indicate whether or not they agree to take part in the study. The recording will be kept as proof of verbal consent until written consent is obtained. The recording will then be destroyed. At the patient's first visit to the CHUM (week 1 or 3, depending on the option chosen), the patient will be asked to sign the ICF.

<u>Telephone script for initial contact:</u>

Dear Mr or Mrs X,

My name is X and I am a research assistant working under the supervision of Dr Nicolas Garel a psychiatrist and researcher at the CHUM. I am contacting you because of your treatment at the ketamine clinic. I would like to speak with you about a psychotherapy research study that we are undertaking for research purposes. The answers you give will in no way influence your clinical care so please feel totally free to give any response, including that you do not wish to speak further about this matter. May I introduce this study?

We are currently recruiting 30 patients who will receive ketamine therapy for treating depression that has not improved with previous treatments. In this study, we aim to add 8 weekly sessions of a known therapy called Acceptance and Commitment Therapy to the ketamine treatment that you will receive in

the clinic, with the goal of exploring whether combining this therapy with ketamine can improve the results.

Participation in this research project involves:

- *Attending 8 weekly therapy sessions, provided by our team, in addition to the ketamine sessions you are scheduled to receive.*
- *Sharing relevant medical and therapy-related information (with appropriate confidentiality measures) so the research team can compile it into an anonymized database for analysis.*
- *Allowing the research team to produce one or more scientific publications based on the anonymized data.*

Your confidentiality will be protected at all times; we will take rigorous steps to ensure all data are de-identified before analysis. Your participation is entirely voluntary, and refusal to participate will in no way impact your clinical care at the CHUM or elsewhere. This study has been reviewed and received ethics clearance from the [Institutional Review Board / Ethics Committee name & reference number].

If you are interested in learning more or wish to participate, I would be happy to schedule an online meeting to explain the project in detail, answer all of your questions, and obtain your formal consent. This meeting would likely take about 30-45 minutes. After you consent, we would proceed with scheduling your therapy sessions in coordination with your ketamine sessions.

Thank you very much for your time, and please feel free to let me know your preference.

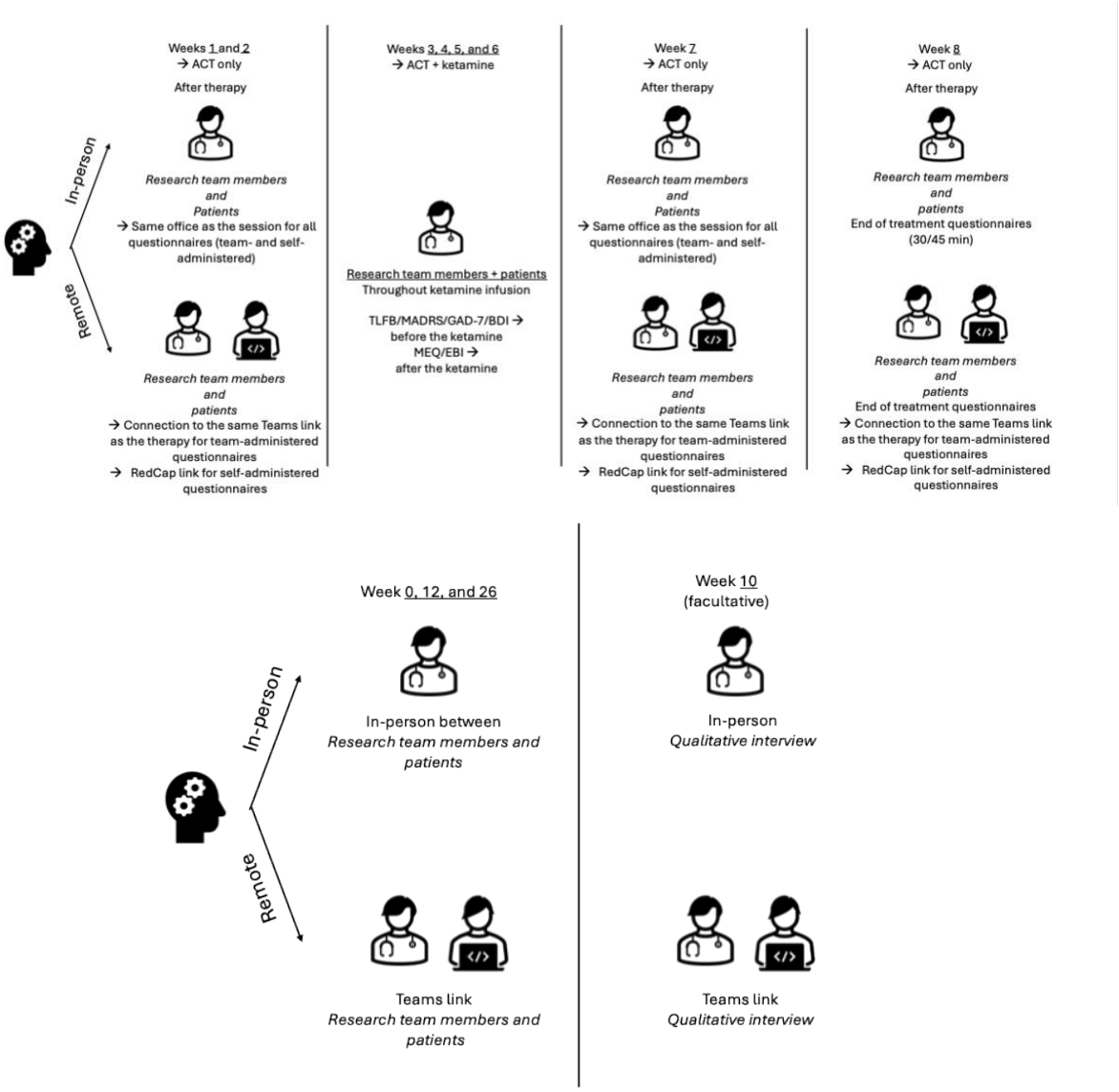
Sincerely,

At the time of consent, the patient will be offered the options of receiving in-person versus remote, virtual ACT sessions. Depending on the option chosen, the procedure for administering the questionnaires will be as follows:

- If the patient chooses the in-person option, they will visit the CHUM clinic 8 times (8 ACT sessions), in addition to their 4 ketamine treatments, for a total of 12 visits in 8 weeks.
    - For the weeks of ACT therapy only without ketamine administration (weeks 1, 2, 7, and 8), the participants will be met by a research team member to complete the TLFB/MADRS questionnaire (team-administered) and the other self-administered scales via an iPad on RedCap **after completing their session,**
        - This will involve a supplemental 30/45 min after their therapy, for a total visit of 1h45.

- For the weeks of ACT therapy and when ketamine is administered (weeks 3, 4, 5, and 6), participants will complete questionnaires before and after their infusion session. They will complete the TLFB/MADRS/GAD-7 and the BDI before the ketamine infusion, and the MEQ/EBI after the ketamine infusion.
    - Hospital visits for ketamine infusion involve a lot of waiting time for patients. These waiting times (taking vital signs, waiting before and after the start of the infusion) will be used to ask participants to complete the questionnaires, either by a research member or via RedCap on iPad provided by the research team.
    - It is estimated that a visit for ketamine infusion lasts an average of two hours, and that participants will be asked to stay only 30 to 45 minutes longer than usual (therefore, a total visit of 2h45).

- If the patient chooses the remote option, they will visit the CHUM only for their ketamine treatment. ACT sessions will be provided through a governmental Microsoft TEAMS account.
    - For the weeks of ACT therapy only (weeks 1, 2, 7 and 8), participants will complete the TLFB/MADRS with a research team member on the same Teams link used for the therapy, after its completion. They will also receive a RedCap link to complete the self-administered questionnaires. The participants will be asked to answer these questionnaires on the same day of the therapy.
        - This will therefore involve a 1 h ACT session provided through Teams plus a 15 min for questionnaire completion with a team member, as well as a 30 min window to complete the RedCap questionnaires from home.
    - For the weeks of ACT therapy and ketamine infusion (weeks 3, 4, 5, and 6), questionnaires will be filled at the hospital with the same procedure as already described.
- The participant's choice (in-person or remote) will also be respected for visits that are outside the 8-week treatment period; visits 0, 12 and 26.



- Study assessments are intended to assess eligibility and measure the outcomes of interest as efficiently as possible, minimizing participant burden. The schedule of procedures and assessments is presented in the table below.

Below is a summary table of the visit schedules. The scales used to check outcomes will be described later in this protocol.

				Weeks												
				0	1	2	3	4	5	6	7	8	9 10	12	…	26
	ACT				✓	✓	✓	✓	✓	✓	✓	✓				
	Ketamine						✓	✓	✓	✓						
	Assessments	# items	Expected completion time (min)	0	1	2	3	4	5	6	7	8	9 10	12	…	26
Alcohol-related outcomes	AUDIT	10	5	✓								✓		✓		✓
	TLFB	N/A	15	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓		✓
	ACQ-NOW	47	10	✓								✓		✓		✓
	OCDS	14	15	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓		✓
	SOCRATES	19	6	✓								✓		✓		✓
	AASE	12	5	✓								✓		✓		✓
Mental health-related outcomes	MADRS	10	15	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓		✓
	BDI–2	21	15	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓		✓
	GAD7	7	3	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓		✓
	BSS	19	15	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓		✓
Psychedelic experience-related outcomes	MEQ	30	10				✓	✓	✓	✓						
	EBI	6	6				✓	✓	✓	✓						
	FFMQ	39	15	✓								✓		✓		✓
Psychotherapy-related outcomes	MODTAS	34	10	✓												
	WAI-SR	12	5		✓	✓	✓	✓	✓	✓	✓	✓				

	WAI-SRT (completed by the therapist)	10	5		✔	✔	✔	✔	✔	✔	✔	✔				
Quality of life/Functioning	EQ-5D-5L	6	3	✔								✔		✔		✔
	WHODAS 2.0	36	6	✔								✔		✔		✔
Qualitative assessment (Facultative			60/90										✔			
Total expected completion time (min)				120	75	75	90	90	90	90	90	120	60/90	120		120

4.3.2. Variable d'intervention ou d'exposition *(Intervention or exposure variable)*

4.3.2.1. Expositions ou interventions – Devis autre qu'un essai clinique *(Interventions or exposures – Other study designs)*

8-week ACT therapy plan

The therapy will be provided through 8-weekly 50 minutes sessions over 8 weeks duration because of its practical and ecological value, and because it's a common psychotherapeutic intervention format delivered in Public Health Systems. ACT therapy requires to perform in session experiential exercises, including mindfulness exercises, which are more compatible with face-to-face format. The therapy will thus be encouraged to be provided on-site, but virtual format will be accessible.

ACT is anchored in an integrated radical behaviorism and existential approaches intended to target and treat common and transdiagnostic drivers of psychological suffering. ACT is thought to have a transdiagnostic therapeutic effect by increasing psychological flexibility, by engaging patients in a valued and meaningful direction of change, and by acting on common maladaptive cognitive and behavioral avoidance processes. The common aim of ACT interventions are: "(de)fusion, evaluation, avoidance, and reason giving". *Fusion* refers to the common human experience of over-reliance on beliefs and thoughts over direct experiences. *Evaluation* refers to the evaluation of our experiences as wanted or unwanted, and attempts to *avoid* thoughts, feelings, memories of unwanted experiences, which can amplify and create the experience of suffering (e.g. drinking alcohol as a way of avoiding painful experiences). *Reason-giving* is the action of coming up with reasons why we can't or shouldn't change our behaviors. The development of psychological flexibility in ACT is cultivated through attention on six core processes and exercises: acceptance of one's experiences, values clarification, the identification of specific behaviors in the service of those values (committed action), present-moment awareness, defusion from the literal belief in one's thoughts and contact with a flexible experience of the self (self-as-context). Every session will be characterized by a theoretical discussion / transmission of therapeutic concepts by the therapist, and by experiential exercises.

The 8-week ACT therapy intervention was created and designed by two experienced ACT psychologists. The table below summarizes the themes / topics of each session, from week 1 through 8. A detailed manual guide will be produced for therapists to describe specifically each session, the therapeutic content needed to be covered, and imaginative transcripts to operationalize it. The decision to use well trained psychologist / psychotherapist in ACT was made to increase therapy fidelity.

Themes / exercises		1	2	3	4
Weeks	1	Joining the D.O.T.S (Distraction, Opting out, Thinking strategies, Substances)	Presentation of the 6 basic ACT processes as well as the matrix	Exercises: self-observation journal and anchoring (“jeter l’ancre”)	Teaching mindfulness
	2	Start with a mindfulness exercise and Feedback on the exercises	Presentation of emotions, including shame and consumer situations leading to shame.	Introduce the concept of acceptance and its 5 steps: resist, recognize, allow, welcome, adapt.	Give a diary of the week as an exercise in learning to accept.
	2 (optional)	Start with a mindfulness exercise and Review the exercises.	Introduce the choice point (moving closer, moving away),	Introduce the concept of control and struggle, and the quicksand metaphor	3N exercise (naming, noting, neutralizing)
	3	Start with a mindfulness exercise and Review the exercises	Introduce shame and the link with consumption	Reminder of session 2, write your shame profile.	Exercise on exploring shame during the week.
	4 and 5	Start with a mindfulness exercise and Look back on the experience and exercises	Make the link with values, present and clarify them.	Do a guided visualization of how you want to celebrate your 20th anniversary of recovery or your 80th.	Exercise: Bull’s-eye.

	6	Start with mindfulness exercise and Feedback on exercises	Activation and action, link with values and objectives,	SMART objectives (Specific, Measurable, Achievable, Relevant, and Time-Bound)	Exercise: SMART goals and obstacles.
	7	Mindfulness exercise, feedback, and compassion.			
	8	Start with mindfulness exercises, feedback and Reflections	Relapse prevention, therapeutic achievements, tools in the safe box.	Managing cravings, the wave, the moment of choice.	SOBRE breathing exercise (stopping, observing, breathing, responding vs. reacting, evaluating with the vision of the eagle).

Concomitant therapy

Ketamine intervention is not part of the research protocol and is provided in a medical setting at the CHUM neuromodulation ketamine service. The CHUM provides this treatment since 2018 to patients across the province of Quebec.

In summary:

The ketamine treatment procedure consists of four infusions given over four weeks. The treatment protocol consists of a dose of 0.5 mg/kg of ketamine, according to clinical information (i.e., weight, height and BMI), and 40-minute infusions.

Ongoing assessments of patients' physiological and mental status before, during and after the infusion process are conducted.

4.3.3. Variable(s) de résultat *(Outcome variable)*

Primary Outcome

Patient adherence

Secondary Outcomes

Capacity of recruitment: Recruitment rate and consent rate

Tolerability/Attrition rate

Safety

Data collection rate

Resource utilization

Number of patients engaging in ACT in between therapy exercises.

Exploratory Outcomes

Alcohol-related

Alcohol Use Disorder

Remission of AUD

Alcohol use

Frequency

Quantity—Number of drinks per drinking day

% Heavy drinking days

% Alcohol dose reduction

Alcohol cessation rate

% Abstinent day

Reductions in drinking risk level [WHO]

Craving

Motivation

Self-efficacy

Mental health-related

Depressive symptoms

Anxiety

Suicide Ideation

Ketamine experience-related

Mystical Experience

Emotional Breakthrough

Mindfulness

Psychotherapy-related outcomes

Absorption

Working Alliance

Quality of life/functioning

Quality of life

Functioning/disability

4.3.4. Variables démographiques et cliniques *(Clinical and demographic variables)*Demographic Questionnaire

A demographic questionnaire will be administered at the screening visit to collect basic demographic information (e.g., age, ethnicity, sex, gender, education, employment and housing).

A review of medical records is also planned to provide additional verification of demographic and health data (including complete psychiatric diagnoses).

Locator Form

Participants will complete a Locator Form, which will be used to contact them to remind them of follow-up visits and locate participants who cannot be found. For this purpose, participants will be asked to provide their personal contact details (e.g., email, telephone number) and the contact details of other

persons of their choice (e.g., treating team, family member, friend). In addition, participants contact information will be updated at every study visit for the duration of the trial. This information will be collected at the screening. No information from this form is used in data analyses and identifiable information will be accessible only at a site level only and stored in a database separate from the research data.

4.3.5. Covariables *(Covariates)*

Adjusting for Covariates

This feasibility study does not involve an adjustment for covariates.

4.3.6. Conduite de l'étude et stratégies spécifiques de minimisation des biais *(Study conduct and specific strategies for minimizing biases)*

STUDY PROCEDURES

Screening (Weeks -4 to -2)

Potential participants will be identified by the clinical staff and permission to be contacted for research purposes will be confirmed. A screening form will be completed by clinic staff or psychiatrist to collect information on participant medical eligibility for the trial. If medical eligibility is confirmed, this form and information will be sent to the research staff and a full-screening visit will be scheduled and full eligibility will be confirmed. Information gathered in the screening form will be entered into REDcap. Contact information will be collected for the purposes of scheduling the full screening visit and will be entered into REDcap, and this information will only be accessible at the site level. The participant's psychiatrist will be contacted by the study staff directly, as part of the screening process.

Once candidates have been identified, initial eligibility has been confirmed, and a referral to the study has been made, the screening visit will be scheduled. The screening form completion and screening visit can take place either on the same day or on different days (based on staff and candidate availability). During the screening visit, research staff will obtain full written informed consent from the candidate (see Section 9.2). After consent is obtained, screening assessments will be reviewed to confirm eligibility. The screening visit could take up to 1 hour to complete.

If the potential participant cannot complete the screening process or does not meet eligibility criteria within the 14-day screening period, but may be eligible at a future date, the participant may be re-screened at the discretion of the Principal Investigator.

Eligibility will be assessed through the inclusion and exclusion criteria that are specific to this study (underlined in Sections 8.1 and 8.2). Eligibility will be continually assessed as appropriate. Only participants who continue to meet study eligibility criteria are allowed to continue with the screening process. A sociodemographic questionnaire and a medical/psychiatric history will be conducted for that purpose, including confirmation of psychiatric and substance use disorders from treating clinicians. Given the behavioral nature of the intervention, pregnancy and outcomes will not be followed over the course of the trial and will be monitored in the context of their ketamine medical treatment.

Treatment Initiation

If the participant does not initiate their assigned treatment within the 2-week window, this will be considered a treatment initiation failure, and clinical care will be provided as usual. The clinical team will be informed of treatment failure and will be instructed to provide intervention for TRD/AUD as clinically indicated.

Informed Consent Process

The written informed consent to participate in the study is obtained during the screening visit. An adequate amount of time will be allocated for the consent process. The research staff will ensure that the participant understands the information provided in the consent form and will be available to answer questions while participants are reviewing it. Moreover, the research staff will proactively review the consent form with the candidate by asking the candidate to respond to a brief consent quiz (brief 2–3 questions). The purpose of the consent quiz is to assess comprehension of the voluntary nature of participation, study purpose, study participation requirements, and risks and/or potential benefits of the trial. The research staff will review incorrect answers with the candidate until comprehension is exhibited. Once the participant signs the consent form, they will be offered a copy to keep for their records. The research team may also include in the consent form a question inquiring about interest of the participant to be contacted in the future about other research studies. In the case of study visits conducted via telemedicine, e-consent and verification of comprehension will be obtained from the participant through the REDCap EDC system.

Baseline Visit (Weeks -2 to 0)

Once screening assessments are administered, ICF is obtained and eligibility is confirmed, candidates will complete baseline assessments. Baseline assessments could take up to 2 hours to complete and may be done in-person or using telemedicine with the study staff. Screening and baseline

assessments can take place on the same day or separate days. Baseline assessments to be completed are included in the Table of Scheduled Assessments. The period for baseline assessments to be completed is 14 days from confirmation of eligibility.

Data collection

The baseline and follow up assessment data will be collected via REDCap; if it is not possible for the participant to attend these visits in person, telemedicine may be used to conduct the visits. In both cases, data will be directly recorded in REDCap.

Adverse Events (AEs) and Serious Adverse Events (SAEs)

The Principal Investigator Dr. Nicolas Garel is responsible for study oversight, including ensuring human research subject protection, by designating appropriately qualified and trained study personnel to assess, report, and monitor AEs.

Adverse Events (AE) during the study timeframe (from enrolment to week 26) will be assessed and documented by study staff as per the Medical Dictionary for Regulatory Activities (MedDRA). AEs reported by the participant will be recorded by study staff on REDcap and reported to the Principal Investigator (Site PI), study nurse and/or study clinician for assessment and referral as appropriate.
If a reported AE suggests medical or psychological deterioration, it will be brought to the attention of the PI for further evaluation. Safety events that are reported as related to the intervention will be medically managed at the discretion of the referring physician through receipt of the usual services.

Overview of adverse events that can occur during a psychological intervention

It is expected that the ACT intervention will have minimal side effects. Unlike certain psychotherapies (e.g., Trauma-Focused Cognitive Behavioral Therapy) that encourage patients to revisit difficult past experiences, ACT remains centered on the present and the development of psychological flexibility—accepting emotions, clarifying values, and moving toward meaningful actions. By nature, ACT does not require in-depth reliving or negotiation of traumatic content, making it less likely to provoke intense emotional distress. Nonetheless, all therapists will be trained to recognize and manage any challenging reactions, including the potential emergence of heightened self-awareness.

In our specific ACT-based therapy protocol, participants follow a structured eight-week progression. Each week is designed to introduce and reinforce core ACT processes (e.g., clarifying personal values, managing cravings, developing self-compassion, and learning to accept difficult emotions). The therapy is thus anchored in concrete exercises and journaling tasks that help patients apply ACT principles

in day-to-day life. Rather than reliving trauma, participants learn how to respond differently to distress—through acceptance, defusion from unhelpful thoughts, and committed action aligned with personally meaningful goals.

Additionally, combining ACT with ketamine may provide *added value* and *reassurance*. Ketamine infusions can sometimes induce powerful or unsettling experiences for patients; an ACT-trained therapist can offer real-time support and coping strategies to help participants navigate these events safely and constructively.

Study participation also involves completing various questionnaires, which could give rise to negative emotions or fatigue due to their length and reflective nature. To address this, the study team will remain flexible: participants will be given breaks if needed and encouraged to resume the questionnaires at their own pace. A member of the research team will be present or available during questionnaire completion to help manage any distress or fatigue that may arise. This personalized support will ensure participants' comfort and well-being throughout the study.

Premature withdrawal of participants

The Investigator or referring psychiatrist can recommend discontinuation of the intervention for any participant or withdraw the participant from the study if, he/she deems clinically appropriate or, due to either of the following reasons, including but not limited to:

1. Inability or lack of willingness of the participant to comply with the study protocol
2. Serious concomitant illness

Participation is entirely voluntary, and participants may withdraw from the study or end the intervention at any time. If the participant stops his/her intervention, he/she will be invited to remain in the study and continue to attend study visits for the purpose of the intention-to-treat analysis. All participants who discontinue from the study prematurely, regardless of the reason, will be asked to complete the end of study assessments. Participants who are prematurely withdrawn from the study will not be replaced with an equal number of newly enrolled participants. Attempts will be made by research staff to follow up participants for the duration of the study unless he/she withdraws consent. The research team will record and track the information about the number of withdrawals, loss to follow up, protocol deviations, and completed assessments for each visit. This information will be useful for monitoring site compliance and for planning appointments for the on-site research team.

Follow-up

Successful completion of assessments during the 8-week intervention phase and during the 12- and 26-weeks follow-up phase will require proactive measures on the part of the research team to maintain contact with the participant. Updated contact information will be obtained from all participants at the screening visit and include participant's current address and phone numbers, addresses and phone numbers of persons who may know how to reach the participant, including a close family member or friend if participants agree (see Section 10.3 Locator Form). Research staff will update participants contact information at each study visit. During the intervention, regular reminders will be sent. During the follow-up period, the research staff will contact participants to remind them about upcoming assessments. Research staff may call participants and send reminder letters and emails to participants who fail to comply with study procedures.

Loss to Follow Up

The trial aims to minimize loss to follow-up by implementing specific standard operating procedures that outline effective strategies for retaining participants. The research staff will dedicate efforts towards developing a comprehensive retention plan designed specifically to reduce loss-to-follow-up rates

1. Frequent Communication: Maintaining regular contact with participants through phone calls, emails, or mail to keep them engaged and remind them of their importance to the study.
2. Flexible Scheduling: Within the parameters defined in the protocol, staff will make an attempt to provide flexible appointment times as well as the option for "in-person" or "virtual" assessments to reduce inconvenience.
3. Personalized Approach: Tailor communications and interactions to the individual needs and preferences of each participant (e.g telephone calls Vs e-mails).
4. Feedback Loop: the team will offer to share final results from the study with participants where appropriate, so they feel their contribution is valuable and leads to tangible outcomes.

Ancillary services

Referral to community agencies or other local treatment services is already offered to the participant by their ketamine clinical team for additional medical, psychiatric, and substance use services as needed (e.g., primary care, social work, other supportive services).

Study Discharge Considerations for Continued Treatment

Upon completion of the study, participants will be informed that they will continue receiving treatment as usual at the clinic and that the ACT will not be available outside of the study once participation is

complete or discontinued. Upon completion of the study, all participants will be informed that they will continue receiving treatment as usual at the clinic.

Participant Reimbursement

All participants will receive a compensation of $20 for attending the screening assessment, $40 for completing the end of follow-up (questionnaires at 26 weeks) -with or without the qualitative interview- and $20 for completing the 12-week follow-up. The total amount of compensation for all the study visits will be $80.

Retention Plan

Research staff will make the best efforts to follow up with participants to complete post-intervention, and follow-up assessment measures. Communication and contact can be made online, over the telephone or in-person visit, according to local regulatory policies. The visit will only occur if confidentiality can be strictly maintained. All interactions with the participant will be recorded in the participant's file.

4.4. Aspects statistiques *(Statistical aspects)*Taille d'échantillon *(Sample size)*

This feasibility study does not involve sample size and power calculations, considering the primary objective of patient adherence to the intervention.

The National Center for Complementary and Integrative Health [NCCIH] notes that sample size in feasibility/pilot study should be based on "practical considerations including participant flow, budgetary constraints, and the number of participants needed to reasonably evaluate feasibility goals." (117).

The choice of including 30 patients is reasonable for the clinical context of the CHUM ketamine clinic [expectation of 2 to 3 patients per month], and a fair number to evaluate feasibility goals.

4.4.2. Analyse statistique *(Statistical analysis)*

Primary outcome analyses

Descriptive analysis: Patient adherence will be summarized as a categorical variable in terms of frequencies and percentages.

Secondary outcome analyses

Descriptive analysis: The different secondary outcomes will be summarized as a categorical variable in terms of frequencies and percentages.

Exploratory outcome analyses

Descriptive analysis: Descriptive summaries of the distribution of continuous baseline variables will be presented with percentiles [median, 25th and 75th percentiles], and with mean and standard deviation. Categorical variables will be summarized in terms of frequencies and percentages.

Pre-post-intervention:

As there is no control group to this feasibility study, within-group analysis will be performed with paired t-test for continuous variables [i.e., scales mean] or McNemar test [paired chi-square test] for categorical variables [i.e., number of patients above scale threshold].

A more modern and flexible regression-based technique will also be used to account for the clustering (non-independence) of the data attributed to the longitudinal and repeated measures design of this study. This technique can be generalized to accommodate a wide range of outcome data including continuous and categorical variables.

Statistical significance for all analyses will be determined based on two-sided $\alpha = 0.05$.

Qualitative interview:

A thematic analysis is going to be performed. This method enables data to be categorized by using themes to answer the research questions, which enables systematic identification, grouping and linking of themes to create a thematic tree.

Missing data and dropouts

Missing data could occur for the following two types of reasons:

- Missed or illegible item response on case report forms or assessment tools.
- Missed visit.

Reasons for missing data will be coded.

Demographic and baseline characteristics

Baseline demographic and clinical variables will be summarized for all participants. Descriptive summaries of the distribution of continuous baseline variables will be presented with percentiles (median, 25th and 75th percentiles), and with mean and standard deviation. Categorical variables will be summarized in terms of frequencies and percentages.

5. Surveillance et sécurité *(Surveillance and safety)*

Risk Management

Risk is managed/mitigated through several methods:

1. Participants with highly unstable psychiatric conditions, outside of the clinical conditions for which a ketamine treatment is indicated, will not be eligible to participate at the discretion of the psychiatrist.
2. All participants will be provided with clear written instructions on how to seek help if they feel worse as part of the intervention.
3. All participants will be receiving standard of care and will have access to mental health services (a model which includes easy access and rapid response from their clinical team). Psychiatrist and mental health professional support staff will monitor risk and deterioration at every clinical visit and will respond using their usual risk assessment and management algorithms.

A standard operating procedure (SOP) - SOP for the Identification and Management of Adverse Events during Psychotherapy Sessions for Patients with Alcohol Use Disorder and Depression Participating in a Research Study - is now available in **Appendix 1** of the modified protocol.

4. Expertise: The PI has ensured appropriate training/certification and experience of the interventionists in delivering ACT, as well as ketamine treatments.
5. Quality control: A) Case-conferences for therapists will be organized to discuss cases, answer questions and review skills required for each intervention session, ensuring standardization across providers and fidelity to the protocol. B) Post-intervention quality control: Before starting the first therapy session, additional verbal consent will be sought from the participant to allow for recording the psychotherapeutic session. Only voice recording will be performed to limit the potential breach in confidentiality. The recording will be labelled with a code assigned to the research participant and provided to Dr. Nicolas Garel, after every session. Dr Élie Rizkallah, clinical psychologist who collaborated on the manualization of the ACT therapy with Dr. Garel, but who is independent of the research project, will listen the recording, make clinical notes and

delete. A fidelity tool will also be developed to consistently judge the fidelity of interventions over the course of the study. Fidelity tools in psychotherapy must be designed to reflect the particularities of each intervention, as emphasized in the literature (118). General scales already exist, such as the Acceptance and Commitment Therapy Fidelity Measure (ACT-FM) proposed by O'Neill et al. (119) and the Fidelity Instrument for ACT-Based Psychotherapy Sessions for Alcohol Use Disorder. However, these tools were designed for settings and purposes that differ from those of our intervention. While we build on these existing instruments, we customize a therapy delivery fidelity tool that accurately reflects the unique characteristics of our intervention (Appendix 2). We will also assess therapy uptake by asking therapists to systematically record at each meeting whether participants have completed their participant logs and practiced the exercises taught.

Safety Monitoring

Adverse Events

The Principal Investigator will be responsible for overseeing any safety events. These reviews will include an assessment of the possible relatedness of the event to the study intervention or other study procedures. All AEs from the first psychotherapy sessions up to and including the 26-week follow-up visits will be assessed and documented by study staff as per the Medical Dictionary for Regulatory Activities [MedDRA] [see Section 9.5]. The study staff will be trained to inquire about all AEs and potential safety events related to the intervention and reporting procedures to the referring physician and PI. The research team has established practices for managing medical and psychiatric emergencies, and the study staff will continue to utilize these procedures.

Training Requirements

The study staff will be trained to full competency on all assessments and procedures as per protocol. Required training will include Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS-2) and Good Clinical Practice (GCP) as well as protocol-specific training as needed (e.g., assessments, study interventions, safety procedures, data management and collection). All study staff will be required to complete training requirements prior to recruitment and enrollment of participants. Training is an ongoing activity that occurs at all phases of a study, including before the beginning of the study, during implementation, and in preparation for study close out.

Training in study-specific assessments will be provided through a comprehensive training plan that will be developed by the Lead Principal Investigator. All training on the REDCap EDC system and other studies specific training is expected to be delivered via interactive face-to-face format, conference call, webinar, and self-study.

All research staff involved in the trial will participate in one-on-one training sessions for each clinician-rated scale. Additionally, inter-rater variability will be thoroughly reviewed with the principal investigator. This ensures consistency and accuracy across all assessments.

Data deposit:

Data will be coded with the participant's number to avoid identification and preserve confidentiality.

Data will be stored on the REDcap server and the CR-CHUM I folder. Access will be restricted by a password unique to each identifier.

Data will not be shared.

6. Considérations éthiques *(Ethical considerations)*

Research Ethics Board Approval

This study will be conducted as outlined in this version of the clinical study protocol in accordance with the ethical principles outlined in the Declaration of Helsinki, International Conference on Harmonization (ICH) Good Clinical Practice (GCP) Guidelines, and all applicable regulatory requirements. Prior to initiating the study, written local REB approval to conduct the study at each respective location will be obtained. All protocol amendments will be submitted in writing by the investigators for approval prior to implementation. In addition, the REB will approve all consent forms, recruitment materials, and any other study-related materials given to the participant. Progress reports will be submitted to the REB annually (and with each REB amendment) and continuous study approval will be maintained.

Informed Consent

The informed consent process provides essential study information to participants, enabling informed decisions. Trained and authorized staff who will conduct this process will be listed on the delegation form and approved by the REB. Participants will be informed about the study’s purpose, their role, data usage, and security measures. They will be told that this preliminary study assesses the

feasibility and efficacy of adding a psychological intervention to their ketamine treatment. Participants will receive a consent form in their preferred language (English or French) and will have time to read it. Staff will address all questions and the participant along with the research staff obtaining consent will sign and date the form. The original signed forms will be securely stored, and participants will receive a copy. The consent form will be updated with new safety information or protocol changes. Participants can refuse or withdraw from the study at any time without affecting their medical care. Those who withdraw will be treated without prejudice. The study site will maintain signed consent forms for quality assurance and ethics compliance.

Confidentiality

Confidentiality will be maintained in accordance with all applicable federal regulations and provincial laws and regulations. By signing the signature page of the protocol, the PI affirms that the information provided to the Investigator will be maintained confidential and that such information will only be divulged to the REB, the affiliated institution, and the employees that are bound under an appropriate understanding of confidentiality.

All participant-related information including case report forms, assessments, reports, etc. will be kept strictly confidential. All paper records will be stored in a secure locked location and only accessible to research staff. Participants will be identified only by means of a numeric study identifier specific to each participant. All computerized databases will identify participants by numeric code and will be password protected.

Participants will be identified by their first name when using the application. Participants' names will only be recorded for the purpose of recruitment. The link between participants' identification number and their names will be kept in a password-protected document accessible only by research staff, and this document will be stored on the CRCHUM secure server. The dataset used in the final analysis will be kept at the CRCHUM located in Montreal, Québec for storing and archiving. Data collected in the context of this project will be kept for a duration of 10 years in line with the requirements of the Fonds de la recherche en santé du Québec. It is expected that the data collected as part of this research project will be published in peer-reviewed journals and presented at scientific conferences. However, it will be impossible to identify participants from the data presented in the latter circumstances.

Inclusion of Gender and Minorities

If difficulty is encountered in recruiting an adequate number of women and/or minorities, the difficulties involved in recruitment will be discussed and different strategies will be put in place, including linkage with medical sites and/or treatment programs that serve a large number of women and/or minorities.

Regulatory Files

The regulatory files will contain all required regulatory documents, study-specific documents, and all-important communications. It will be the responsibility of the site to review and maintain regulatory document compliance prior to study initiation, throughout the study, and at study closure.

Records Retention and Requirements

The regulatory files will contain all required regulatory documents, study-specific documents, and important communications. Regulatory files will be checked for regulatory document compliance prior to study initiation, throughout the study, as well as at study closure.

Audits

The site PI has an obligation to ensure that the trial is conducted according to GCP guidelines and may perform quality assurance audits for protocol compliance. The CHUM REB may inspect research records for verification of data, compliance with federal, provincial and/or local guidelines on human participant research, and assess participant safety.

Study Documentation

Study documentation includes all case report forms, research files, and source documents, monitoring logs and appointment schedules, signed protocol and amendments, REB-correspondence, REB-approved consent form, and signed participant consent forms. Source documents include all recordings of observations or notations of clinical activities and all reports and records necessary for the evaluation and reconstruction of the clinical research study. Whenever possible, the original recording of an observation should be retained as the source document; however, a photocopy is acceptable if it is a clear, legible, and exact duplication of the original document.

Data collection, management and monitoring

The Center for Integration and Analysis of Medical Data (CITADEL) of the CRCHUM will be working closely with this study's data management team and will provide support as needed. The REDCap web-based data entry system will be developed and implemented to ensure that guidelines and regulations

surrounding the use of computerized systems in clinical trials are upheld. The remainder of this section provides an overview of the data management plan associated with this protocol.

Site Responsibilities

The data management responsibilities will be specified by the Data Manager and outlined in the REDCap User's Guide.

Statistical and Data Management Centre Responsibilities

The Redcap web-based distributed data entry system will be implemented. This system will be developed to ensure that guidelines and regulations surrounding the use of computerized systems in clinical research are upheld. The research team will ensure data management, following REDCap User's Guide and will include: 1) development of a data management plan and conducting these activities in accordance with that plan; 2) assist the research team to develop eCRFs for collection of all data required by the study; 3) assist in the development of data dictionaries for each eCRF that will comprehensively define each data element; 4) conduct ongoing data monitoring activities on study data; 5) monitor any preliminary analysis data cleaning activities as needed; and 6) rigorously monitor final study data cleaning. Data will be collected directly in the REDCap system. Data entry into REDCap will be completed according to instructions provided in the protocol. If incomplete or inaccurate data are found, a query will be generated in real time to resolve data inconsistencies during survey completion on REDCap.

Data Collection, Training & Quality Assurance

Data will be collected at the CHUM ketamine service and entered by the designated research staff o into REDcap or directly entered by the participant into the REDcap system. Data entry into the REDcap system will be completed through an iPad given to the participants, according to the instructions provided in the REDcap training manual. The PI and study staff will be responsible for maintaining accurate, complete and up-to-date records, and for ensuring the completion of the REDcap for each research participant. If incomplete or inaccurate data are found, a query will be generated to the designated staff for a response. The data management team will work with research staff to resolve data inconsistencies and errors and enter all corrections and changes into the REDcap system. Data monitoring will take place during regularly scheduled clinical monitoring visits and provided by the Statistical and Data Management team.

Data Transfer/Lock

Once the final data has been entered in the REDcap system, final data quality assurance checks will be conducted, and the study database will be locked prohibiting further modification. The dataset used in the final analysis will be returned to the CRCHUM for storing and archiving. Data lock can take place up to 2 months after trial completion.

Data Collection Instruments

The PI will prepare and maintain adequate and accurate source documents designed to record all observations and other pertinent data for each participant treated with the study product. Data will be collected through both interviews and self-report assessments. Medical source documents will be accessed to confirm eligibility. Data entry into REDCap will be completed according to the instructions provided in the study REDcap Training Manual. The Site PI will be responsible for maintaining accurate, complete and up-to-date records, and for ensuring the completion of the REDcap for each research participant. When data are incomplete or inaccurate, a query will be generated for a response. A member of the data management team will resolve data queries. All collected data, throughout the study, will be reviewed and verified for completeness and accuracy by a second team member supervising the data collecting staff and a monthly report will be submitted to the PI. A copy of the REDcap will remain at the Investigator's archive at the completion of the study.

Privacy

Research personnel will inform participants that all the information collected during the research project will remain strictly confidential to the extent prescribed by law and that at no point will any individually identifiable information be revealed in any research publication or presentation. A potential breach of confidentiality, most notably regarding substance use, could occur and conceivably result in negative legal or social consequences for the subject. Several measures will be taken to protect against such a breach. Participants' name, date of birth and any other identifying information gathered during the study will be stored in source documents and kept under lock. Computerized data will be encoded and held at the CHUM's data-management core in secure, password- and firewall-protected servers. The CRCHUM has extensive experience managing large databases of sensitive information (e.g., patient charts) without any reported breach of security. Only authorized persons having an authentication code have access to the REDCap electronic data management system. Protection, detection, and correction measures are implemented to maintain data confidential. All procedures for the handling and analysis of data will be conducted using good computing practices meeting Health Canada standards for the handling and analysis of data for clinical trials.

Study Timeline

The trial pre-implementation period will be approximately 4 months prior to commencing enrollment. Trial preparation will include developing the data collection systems, developing the manuals of operating procedures, conducting staff training and obtaining REB approval. Recruitment is expected to take approximately 10 months (2 to 3 patients per month, with the objective of including 30 patients) with visits continuing for approximately 16 months (6 months after the last patient is enrolled). Two months will be allowed for data lock after the end of the follow-up period.

Knowledge Dissemination

Using the methodology published by Straus et al. in 2009, we will target all knowledge transfer tools to different audiences and analyze the factors that facilitate or hinder their use. For the scientific community, we will present our results at national and international conferences and publish our findings in an open-access research journal to ensure broad dissemination. We will also create online shareable documents of the protocol, analysis plan, and other research tools.

Our research team members, who are active in addiction networks such as the Canadian Initiative in Substance Matters (CRISM), will leverage these platforms to enhance knowledge dissemination. For participants who opted to receive the results, we will provide a narrative summary in plain language, including charts and graphics to aid understanding of the findings and their impact. Additionally, we will create health cards to explain the study results at an appropriate complexity level and produce video clips accessible via websites and social media. The aim of these videos is to make research results accessible to an even wider audience. The videos will be narrated by team members and will present the main results and follow-ups of the study. These videos will be approved by the ethics committee before being released.

Publications and Other Rights

The CR-CHUM seeks to have clinical trial data of this trial presented and published, regardless of its outcome, at scientific congresses and in peer-reviewed journals.

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Appendix 1

MON pour l'Identification et la Gestion des Événements Indésirables lors des Séances de Psychothérapie pour les Patients atteints de Trouble de l'Usage d'Alcool et de Dépression Participant à une Étude de Recherche

1. Contexte

L'intervention ACT (Thérapie d'Acceptation et d'Engagement) est généralement associée à un faible taux d'effets secondaires. Une revue systématique récente a révélé qu'environ 5 % des patients subissent des événements indésirables (EI) liés à la psychothérapie, tels que l'aggravation des symptômes, l'apparition de nouveaux symptômes ou une dépendance au thérapeute. De plus, environ 2,5 % des patients subissent des événements indésirables graves (EIG), comme l'automutilation ou des tentatives de suicide.

2. Objectif

Cette Mode Opératoire Normalisé (MON) établit les procédures d'identification et de gestion des événements indésirables potentiels survenant lors des séances de psychothérapie dans le cadre d'une étude de recherche impliquant des participants souffrant d'une dépression réfractaire au traitement comorbide à un trouble de l'usage d'alcool.

3. Définitions

Événement indésirable (EI) : Toute manifestation médicale importune qui est observée à la suite de l'administration des séances de thérapie, sans qu'il y ait nécessairement de lien causal entre la manifestation et l'administration de la psychothérapie. Un événement indésirable peut donc correspondre à tout signe défavorable et non intentionnel, symptôme ou maladie, temporellement associée à l'administration d'une séance de psychothérapie, qu'il soit ou non considérés comme relié à celle-ci.

Événement indésirable grave (EIG) : Un EI dont les conséquences sont le décès, la mise en jeu du pronostic vital, la survenue probable d'un déficit fonctionnel permanent, une hospitalisation ou une prolongation de l'hospitalisation.

4. Procédure

L'observation et la documentation systématiques visent à fournir un compte rendu détaillé des événements vécus par les participants.

4.1 Préparation de la préséance

L'investigateur principal (IP) s'assurera que tous les thérapeutes sont formés au processus d'identification et de signalement des EI.

Les patients recevront des informations sur la procédure à suivre pour contacter le personnel de recherche en cas d'EI survenant avant ou entre les séances.

4.2 Surveillance pendant la séance

Les thérapeutes surveilleront activement les signes de détresse ou de réactions inattendues chez les participants.

Tout EI observé ou signalé sera documenté dans le dossier du participant.

4.3 Identification des EI

Les EI potentiels seront classés en deux catégories :

4.3.1 Événements indésirables

4.3.2 Événements indésirables graves

Seront considérés comme EI potentiels :

- L'aggravation des symptômes existants, tant dans la sphère dépressive que dans le trouble d'usage de l'alcool.
- L'apparition de nouveaux symptômes, autant de la sphère dépressive que du trouble d'usage d'alcool
- L'augmentation de la consommation d'alcool
- Les idées ou comportements suicidaires
- Une détresse émotionnelle importante
- La nécessité de se présenter à l'urgence ou être hospitalisé

4.4 Signalement des EI

Un rapport initial sera rédigé conformément au Dictionnaire médical des activités réglementaires (MedDRA).

Ce rapport sera soumis via RedCAP à l'investigateur principal dans les 24 heures suivant la prise de connaissance de l'événement.

Un rapport final d'EI sera complété une fois l'événement investigué et géré.

4.5 Gestion des EI

L'équipe clinique sera informée de l'EI si elle n'est pas déjà au courant.

Des soins appropriés seront prodigués jusqu'à la résolution de l'EI, et leur gestion sera documentée.

En cas d'interruption nécessaire de l'intervention de l'étude, le protocole de sortie de l'étude sera suivi.

4.6 Évaluation des EI

L'IP et l'équipe clinique examineront les événements indésirables.

Les membres du panel fourniront des évaluations indépendantes concernant :

- Le type d'événement
- L'évaluation de la gravité
- La relation avec le traitement de l'étude
- Un consensus sera établi entre les membres du panel sur les évaluations des EI.

4.7 Suivi et analyse

L'évolution du patient sera surveillée et tout changement dans son état sera documenté.

Les EI seront analysés pour tenter d'identifier la présence de tendances/patterns afin d'

Des actions correctives seront mises en œuvre et surveillées si nécessaire afin d'améliorer la sécurité des patients.

5. Documentation

Des registres complets de tous les EI seront tenus, incluant :

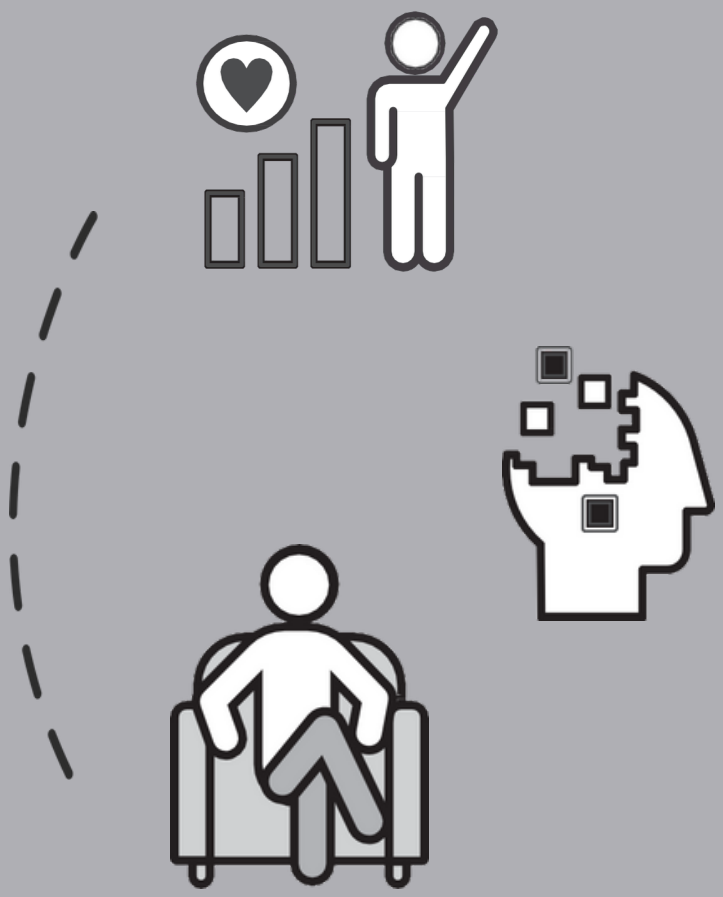
- Les rapports initiaux et finaux d'EI
- Les dossiers médicaux liés à l'EI
- Les évaluations des EI par le clinicien/IP
- Les actions correctives prises

6. Rapport et mise à jour du comité d'éthique

Les EI seront signalés au fur et à mesure de leur survenue. Le comité d'éthique recevra des mises à jour à mesure que les EI seront résolus ou que d'autres actions seront jugées nécessaires, telles qu'un traitement d'urgence, une hospitalisation ou l'arrêt de l'intervention.

7. Formation

L'IP s'assurera que tout le personnel de l'étude est formé à cette MON et comprend ses responsabilités dans l'identification et la gestion des EI



THERAPIST'S MANUAL

Weeks 1 to 9

An evolving, patient-adapted acceptance and commitment therapy

CRCHUM
CENTRE DE RECHERCHE

CHUM
Centre hospitalier de l'Université de Montréal

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This document uses the masculine gender to denote all genders, in order to simplify the text

Table of Contents

An evolving, patient-adapted acceptance and commitment therapy

WEEK 1

I’m specifying the direction I want to take

WEEK 1 — I'M SPECIFYING THE DIRECTION I WANT TO TAKE

Objective

✓ Presentation by the client about what the problem is, his perspective of what he wants. Steer the client towards discussing his substance use problems.

✓ Succinctly present the point of view of the ACT matrix with its different components as a tool of self-observation and change (STOP-OBSERVE-CHOOSE):

- experience of sensations and behaviours (above)
- experience of inner world (below)
- values (who and what is important) (below and to the right)
- inner obstacles (thoughts, emotions, memories that I don't like having)
- committed actions (approach),
- fighting actions (distancing),
- ME who observes and chooses at the center of this point of view

✓ Present the perspective of ACT—The question of choice in life and learning to cope with obstacles in order to create the life we want to live, rather than trying to eliminate what might seem difficult.

✓ Have the client, during the week, observe their experiences through the matrix and identify approach and distancing actions.

Material

Documents to use and/or give to the client:

- ACT matrix (self-observation tool).

Notes/instructions for the therapist

1. **Start with an explanation of the therapy**
2. **Determine the presenting problem (around 10 to 12 minutes)**
   - Therapist's tool: What brings you in?
   - Excerpt from the book: Guide de la matrice ACT p. 42-49.

Eg.: "To help me know you, let's start, if you like, by talking about the reason that you are here. What you find isn't working in your life. The behaviours you want to adopt and their impact on your personal, family, or work life?" While he shares, write the answers on the matrix without sharing them for the moment. Finish by summarizing what he just described to you until he confirms that you have properly understood. Ask also for something that he likes about himself, a quality, a characteristic, and reflect e.g.: you are empathetic, is that what you mean? (Around 10 minutes).

WEEK 1 — I'M SPECIFYING THE DIRECTION I WANT TO TAKE

Notes/instructions for the therapist (continued)

3. **Present and succinctly fill in the ACT matrix:**

   Afterwards, propose presenting a perspective (also called the perspective of psychological flexibility), a tool for self-observation and change, that some people facing similar difficult situations have found useful for advancing their lives.

   Present the ACT matrix and fill it in together. The objective here is to succinctly present the tool and its observations.

4. **Ask the question of which life to choose: reaching a shared vision of therapy (around 5 minutes)**

   - Title of the book: guide de la matrice ACT p. 49-50.

   End the presentation of the point of view of the ACT matrix by asking about the choice of life:

   "If you had a choice between two lives—one life where most (but not all) of your actions were done to bring you closer to the people and things that are important to you (point to the bottom right of the matrix) or one where most of your actions were made to distance you from these (point to the bottom left of the matrix), what life would you choose?"

   The majority of people will respond that they would choose a life to get closer. Sometimes, people who are suffering more or who have lost hope will pick a life on the left. In this case, we recognize that the life of the person is so difficult that they have lost sight what it could be to live more on the right. We tell him that, even if we cannot make what is happening on the bottom left disappear, we can explore ways to deal with our difficult thoughts and feelings.

   "Would you like to learn to more often choose these actions (point to the top right) even in the presence of these things? (point to the bottom left of the matrix).
   That's what we are proposing—not to make the inevitable waves of the ocean disappear, but rather to surf those waves."

   Highlight to the client that the objective of the eight Acceptance and Commitment Therapy sessions is to help him adopt a different position in regards to his difficult interior experiences, to change his response to his experiences, to better make room for them and commit to actions that support a life that is in accordance with what is important to him.

5. **Stop-Observe-Choose**

   We will go step-by-step. We will, to start, slow down a bit and observe what is going on inside and outside of yourself, take a step back from what is happening in the matrix, that means in your head, in your heart, in your body and in your actions. Little by little in your observations of yourself, you will begin to CHOOSE actions that you want to take. CHOOSE in the sense of ACTING instead of REACTING automatically...

WEEK 1 — I'M SPECIFYING THE DIRECTION I WANT TO TAKE

Notes/instructions for the therapist (continued)

6. **Suggested exercises of the week (around 5 minutes)**
   Observe the approach and distancing actions that present themselves during the week.

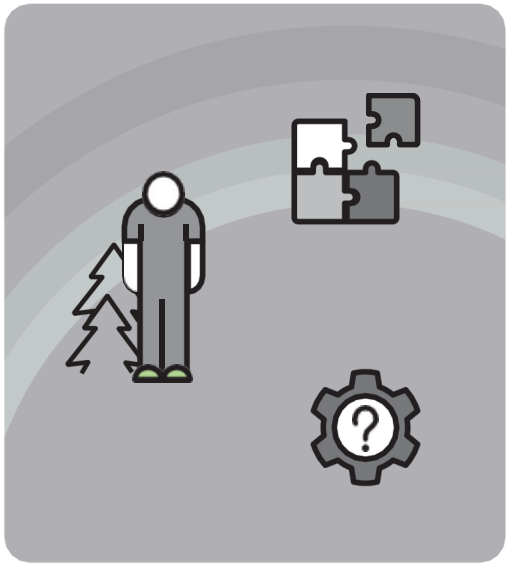
   Encourage the client to commit to their course of action and take ownership of it daily
   Cognitive flexibility can be practiced!

7. **Feedback (around 1 minute)**
   What is the thing that you retain from today's session?

Session adapted from:

Polk, K., Schoendorf, B. Webster, M. & Olaz, F. (2017). Guide de la matrice ACT. Deboeck ; Belgique.

An evolving, patient-adapted acceptance and commitment therapy



WEEK 2

Why isn't it working?
Distancing behaviours

WEEK 2 — WHY ISN'T IT WORKING

Distancing behaviours

Objectives

✓ Discuss the reasons for using substances.

✓ Help the client to identify experiential avoidance (escape) of experiences by bringing up the role of substances.

✓ Help the client think about the short and long term impacts of the diverse strategies he uses to manage thoughts, emotions, and difficult sensations.

✓ Bring about an understanding of what triggers and maintains these difficulties.

✓ Encourage moving towards handling what seems difficult to him differently (with what presents itself in the bottom left instead of against it) and engage in actions that go in the direction of what matters.

Material

Documents to use and/or give to the client:

- Join the DOTS, if necessary (for clients who are not very expressive)
- Matrix
- Self-observation journal

Notes/instructions for the therapist

1. **Start with a short mindfulness exercise (around 3 minutes)**

   Focus attention on his breathing (inhalation and exhalation) while noticing that thoughts and emotions can come up. Bring back attention, without judgment, on the breath.

2. **Feedback on the observations from the previous week (around 5 minutes)**

   Reinforce all observations or classifications in one of the matrix quadrants (e.g. super, great observations!). Invite them to identify an approach and a distancing behaviour and the impacts of those actions (e.g. great, you recognized that it was a...action! And were you able to observe what resulted from doing this action?)

3. **Substance use as a tool:**

   The objective is to bring out that the main function of substance use is avoidance of difficult or unpleasant interior experiences or automatic responses associated with triggering stimuli.

   "Most things that we choose to do in life have a goal (obtaining a certain result). Drugs and alcohol are not different. They serve a goal, a function. We could consider the use of substances like something that you use because it has an enjoyable consequence or diminishes something that is unpleasant."

WEEK 2 — WHY ISN'T IT WORKING?
Distancing behaviours

3. Substance use as a tool: (continued)

Just like a hammer can be used to put nails in wood and a saw can be used to cut wood, substance use had, for you and all other people like you, a certain "function," often a search for something pleasant or an attempt to not be in contact with something unpleasant.
How would you complete the following phrase?

For me, the role that alcohol has had up to now has been:

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Presently, what are the consequences of your alcohol use?

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Common themes that can emerge are:

To feel better, self-medicate, escape, control your emotions.

For clients that share positive reasons like euphoria, it can be useful to proceed with a quick behavioural analysis, for example:

When do you usually seek out euphoric feelings?

How do you usually feel right before you drink?

If you did not drink, what would the consequence be?
What could happen? How would you feel?

Have there been changes in the results produced through time?
Do some types or contexts of use produce similar outcomes, or different ones?

The manner in which we drink can produce effects that we like, like euphoria, and at the same time effects that we don't like (e.g. embarrassment, shame, etc.). The balance between positive and negative effects can vary through time.

Highlight the fact that the client has tried to change/control/get rid of/erase difficult, painful or uncomfortable experiences with substance use, and note for yourself elements that you can triage later in the matrix quadrants.

WEEK 2 — WHY ISN'T IT WORKING?

Distancing behaviours

4. Participate in the exercise "Connect the DOTS": What have you tried when you don't feel well?

The objective is to help the client identify the emotions, thoughts, images, and memories that sometimes invade him and what he tends to do when he is in their grip. We are preparing the groundwork for the impact evaluation that we will do later with the matrix.

We have all tried different ways to face or manage these difficulties in our lives. And, I imagine that you have tried different methods to control, manage or stop your substance use. I would like to take a few minutes to think through the diverse strategies that you have tried.

Exercise with the client:
Join the DOTS–What have you tried?

- What methods have you used?
- How did they work for you?

Note: **Do not begin** to judge these methods as being "good" or "bad", "positive" or "negative." The objective is simply to determine the methods that you use the most often. We will consider later if these methods are **useful for you**. What are the thoughts, feelings, sensations, memories, primary emotions that you don't like to feel or that have a hold on you?

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Leave some time for the person to think, then write it down with them in the matrix.
We will now look at various types of behaviours that people can adopt in order to face what is uncomfortable for them or when they are under the grip of difficult thoughts, memories or emotions.

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WEEK 2 — WHY ISN'T IT WORKING?

Distancing behaviours

Informal exercise, only a memory aid for the therapist.

D — **D**istraction: What do you do to distract yourself or to try to forget your painful thoughts and feelings?
For example: movies, television, internet, books, computer games, physical activity, gardening, gambling, food, drugs, alcohol, etc.

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O — **O**pting out: What are the activities, events, tasks, challenges or important people who improve your life that you avoid, abandon, run from, put off to tomorrow or that you pull away from?

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T — **T**hinking strategies: How do you try (consciously or not) to escape pain or suffering? Check off all of the elements that you have previously used and write down any other strategy that is not in the following list:

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Thinking strategies: Ruminating on the past, fantasizing about the future; imagining escape scenarios (for example, quitting your job or leaving your partner) or revenge scenarios; telling yourself "this isn't fair…" or "if only…"; blaming yourself, blaming others, or blaming the world; judging or criticizing yourself; analyzing yourself (trying to understand "why am I like this?"); analyzing the situation (trying to understand why it happened); analyzing others (trying to understand why they are like that); planning; strategizing; solving problems constructively; making to-do lists; repeating inspiring sayings or proverbs; challenging or disputing negative thoughts; telling yourself "this too shall pass" or "this may never happen"; talking to yourself in a logical and rational way; thinking positively; positive affirmations…

S — **S**ubstances: What substance do you use that you use to try to avoid or eliminate suffering?: Food, drinks, cigarettes, drugs, natural and plant-based remedies, over-the-counter or prescription medications, etc.?

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WEEK 2 — WHY ISN'T IT WORKING?

Distancing behaviours

S — **S**trategies: Are there other strategies that you use in response to undesired thoughts or feelings? For example, yoga, meditation, emotional relationships, aggressiveness, massages, exercise, dance, music, prayer, books, self-care, consulting with a therapist, a doctor, or other healthcare professional, attending a support group, calling your sponsor, etc.

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Also, suicide attempts, self-harm, breaking objects, staying in bed, getting angry, lying, inventing stories, etc.?

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Ask the client to bring up the things he does the most in his daily life and place it in the top left of the matrix while making the link between the bottom left and top left quadrant: Ok, you are bored (note I'm bored in the bottom left), you say to yourself that you could have a beer and you start drinking (top left).

Note the actions that he seems to find useful or effective and place them in the matrix (on the right).

5. Evaluate effectiveness:

Title of the book: guide de la matrice ACTp.76-83.

This consists of evaluating, with the help of -,--,---,neutral(0), +,++ or +++ the impact or the effectiveness of the methods used.
Don't explain, just score. It is done directly on the matrix.

We start with the short term. We then pass to the long term.
We then ask the client what seems to come out of these evaluations.

It usually comes out that fighting actions are effective in the short term, but they have little to no effect in the long term. They are often even noted as being ineffective or very ineffective. We can then demonstrate that these actions function in the SHORT TERM (that's why we do them!), but they do not work in the MEDIUM-TO-LONG TERM and even less for getting closer to the people and things that are important to us. It is in this way that we can all find ourselves stuck in these loops (or vicious circles or patterns).

We then draw a loop starting in the left quadrant in the bottom left. So, when one of those things shows up and goes towards the top left, you do one of these actions, right? And, after a certain amount of time, the spiral goes down and then later, it goes back again. When we do it and redo it again and again, life loses its sense of purpose and value.

Propose to the client that they identify one of these vicious circles, loops, spirales (e.g. Marc tells himself that life is hard enough that he might as well have a small drink. Then he drinks the bottle...and then it's Marc that has the difficulty getting up in the morning and who is grumpy and impatient, and who regrets not having stopped himself from drinking and who will drink again...).

Conclude the session with the ACT metaphor of the person in the hole using the client's matrix for visual support (see section 6).

WEEK 2 — WHY ISN'T IT WORKING?

Distancing behaviours

Another way to bring up this point for the therapist:
Join the DOTS — Part 2: How did this work out? What was the prize? What works for me in the short, medium, and long term?

You will observe that many of these strategies soothe your painful thoughts or feelings in the moment or in the short term. But are you ultimately getting rid of these unwanted thoughts or feelings? Do they come back in the short and long term? Are they sometimes followed by regrets, remorse, guilt, embarrassment, shame? Usually, with most of these strategies, for how long does the pain disappear before it returns?

It is clear that some methods help, if you use them in a flexible, moderate and reasonable manner. If that is the case, keep using them!

At the same time, if we overuse these methods, if they become automatisms that we are dependent on, if we use them in an excessive manner, rigidly or not adapted, they have a great cost.

When you have made excessive use of them, what have these methods cost you in terms of your health, finances, lost time, relationships, missed opportunities, work, acute pain, fatigue, wasted energy, frustration, deception, self-confidence, self-esteem, etc.?

You are not lazy or stupid
You have made great efforts for a long time to rid yourself of these thoughts and feelings. No one can say that you are lazy! And you are not stupid! These are methods that everyone uses to some extent to avoid or get rid of pain and suffering. We try to distract ourselves, we all give up on difficult things, we all try to think of ways to get rid of pain and we all introduce substances, in one form or another, into our bodies. What's more, our friends, family, and healthcare professionals often actively encourage us to do all of these things!

However, no matter the efforts we make to avoid or get rid of the thoughts and feelings, in the medium-to-long term, they keep coming back!

WEEK 2 — WHY ISN'T IT WORKING?
Distancing behaviours

Are you stuck in a vicious cycle?
Unfortunately, often what we do to obtain relief from painful thoughts and feelings in the short term has a tendency to make our life harder in the medium-to-long term. In other words, we are stuck in an endless vicious cycle.

Some people have the feeling that they are always doing the same thing that functions in the short term, but that doesn't work at all in the medium-to-long term to diminish their suffering and advance in the direction that they want in life. What's worse, they may have the impression of always sinking down, a little deeper! Though it's exactly the opposite of what they had hoped for.

What thoughts and feelings does this bring up for you? Can you take a moment to recognize how hard it is to be stuck in this vicious circle?

Taking into account that:
a) No matter what you do, your painful thoughts and feelings return
b) Most of the ways that you respond to feelings deteriorate your life in the medium-to-long term
Are you interested in learning another way to respond; a different method from those you have tried to date?

6. Willingness to try another way

You have already worked very hard using diverse strategies to manage these life difficulties that function in the short term, but that bring more suffering/difficulties in the long term.
Let me share a metaphor to explain what I imagine you are living:
Finish with the metaphor of the person in the hole (present in an interactive way):

- Therapist's tool:
- Excerpt from the book: Guide de la matrice ACT p. 86-87.

Imagine that at the dawn of your life, you were blindfolded, given a bag to carry on your back, and asked to walk. You did what was asked, you started to move forward. You could not know what was in your bag and you could not see that you were in a field full of holes. And, one day, you fell into one of those holes. You realized that you could not get out. You looked in your bag and you found a shovel. Shovel, hole. You set yourself to digging (draw the shovel on the left side of the matrix). You tried to dig yourself stairs by (name one of the actions previously noted on the matrix). You tried to dig tunnels (while naming another distancing behaviour previously noted), ramps (in naming another action from the left). You dug in by doing all of these actions (name the other main distancing behaviour).

But since you have been digging, have you noticed the hole get smaller, did you get out?

And what if the shovel was not a good tool for getting out of holes? What could be a better tool for getting out? What about a ladder? Draw a ladder at the base of the matrix to the left and towards the top right of the matrix. What would be the first thing to do to use the ladder? Do you think that if for some time you have been gripping the shovel as if your life depended on it, it might not be so easy to let go of that shovel? What's more, so used to digging, is it possible that you are using the ladder to dig?

WEEK 2 — WHY ISN'T IT WORKING?
Distancing behaviours

Propose that the client share his reflections about the metaphor. If he expresses frustration or confusion, explain that in going through life, he finds himself in a hole of cravings, anxiety, depression, etc. Because he does not want to be, he takes his shovel (meaning substances) and digs some more. The more he digs, the more he sinks. Because it is what he knows, and it seems to him the only option. He keeps going back to his shovel. As long as he clings to his shovel, he will not be able to see other options. Recognize that it can be difficult to lay down his shovel and take the ladder (explore other options).

7. Exercise of the week

Notice when stuck loops are presenting and name them without judgment. Note when they take the shovel (distancing behaviours) or the ladder (committed actions, approach). Encourage the client to fill in his "observation journal" between sessions.

8. Reflection

What is the thing you retained most from today's session?

Session adapted from:

Polk, K., Schoendorf, B. Webster, M. & Olaz, F. (2017). Guide de la matrice ACT. Deboeck ; Belgique.

Harris, R. (2019). ACT Made Simple (2nd ed.). New Harbinger Publications, Inc.: Oakland, CA.

Westrup, D., & Wright, M. J. (2017). Learning ACT for Group Treatment: An Acceptance and Commitment Therapy Skills Training Manual for Therapists. New Harbinger Publications, Inc.: Oakland, CA.

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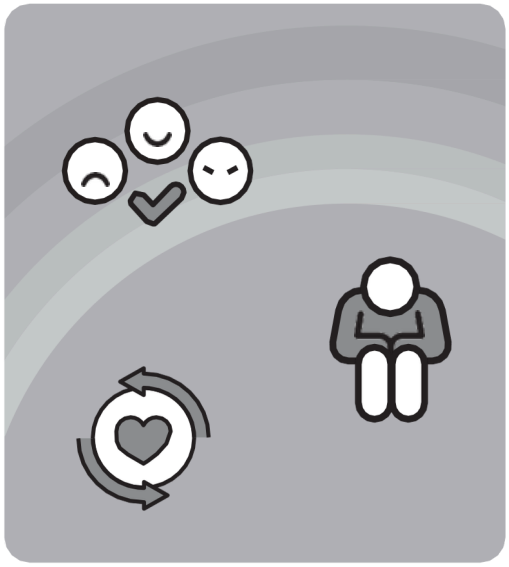
An evolving, patient-adapted acceptance and commitment therapy



WEEK 3

Make room for or fight against

WEEK 3 — MAKE ROOM FOR OR FIGHT AGAINST

Objective

✓ Bring an understanding of the function of thoughts and emotions in humans, as well as our habitual reactions when facing them.

✓ Propose seeing thoughts and emotions for what they are: psychological and mental events rather than objective facts or absolute truths.

✓ Recognize and accept unpleasant thoughts and uncomfortable feelings that may arise. Introduce the idea of making room for these experiences rather than fighting against them.

✓ Explore cognitive defusion and acceptance strategies.

Material

Documents to use/give to the client

- *Verbatim : Guide de la matrice ACT* p. 73-74.

Notes/Instructions for the therapist

1. **Mindfulness exercise (around 3 minutes)**

   Three-minute grounding practice using simple breathing or body-based awareness to prepare for the session. (see *Verbatim : Guide de la matrice ACT* p. 73-74.

2. **Review content from last week and self-observation exercises (around 10 minutes)**

   Review key points from week 2, ask about observations or difficulties, normalize any challenges, and reinforce curiosity.

3. **Why do we have emotions, thoughts and behaviours?**

   Introduce basic evolutionary principles: Humans are not wired for happiness but for survival. Emphasize the distinction between **real** and **perceived** threats.

   Review and discuss the following points:

   ✓ **Emotions are physiological events + mental stories.**

   Every emotion consists of:

   - **physical sensations** (neurological, cardiovascular, hormonal, musculoskeletal changes), and
   - **a story or interpretation** we give to those sensations (narratives, thoughts, meaning-making). Helping patients notice both components supports cognitive defusion.

   ✓ **Physical sensations prepare us for action.**

   Sometimes they create strong urges to react immediately.

   ✓ **All emotions are fundamentally useful–and ultimately benign.**

   Even when unpleasant, emotions evolved to protect us, orient us, and signal what matters. Emphasize the *positive* side of "negative" emotions:

   - **Fear** protects us and alerts us to potential danger.
   - **Anger** signals injustice, unfairness, or violated boundaries.
   - **Sadness** signals caring, loss, and attachment—it only appears when there is love or meaning

   Therapist prompt: "Why do people willingly pay money to watch sad movies?"
   (To illustrate the emotion itself is not dangerous; it can even be meaningful or comforting.)

WEEK 3 — MAKE ROOM FOR OR STRUGGLE AGAINST

✓ **Emotions communicate.**

Through facial expressions, posture, and tone:

- Fear communicates: *Be careful.*
- Anger communicates: *Something is not right.*
- Sadness communicates: *I have lost something important.*

✓ **Emotions drive adaptive behaviour.**

They evolved to help us respond to our environment

- Fear → hiding, protecting oneself
- Anger → standing firm, defending
- Sadness → withdrawing, slowing down, resting

✓ **Note for the therapist:**

Shame is a partial exception and will be explored later in therapy, as its function and impact differ from other emotions.

Take for example the fear of getting punched in the face:

- If you've ever had a fractured jaw after receiving a punch, it's possible that if you see someone with a closed fist, who is imposing and screaming, you will quickly leave.
- However, if you are a boxer, you would charge to make sure that you are the one who lands the first blow.
- These are two extremes that could be calculated based on your life experience, but two reactions that have the same function, to protect you.

Our emotions are not our enemies. We should not try to avoid them because they serve a vital function. Once we have felt them, we have the choice of how we want to react, direct our actions ourselves or allow the emotion to take control.

The control we want and try to have on our emotions (especially those that we perceive as negative and that we don't like having!)

We all hear messages from our families, our peers, from society, about emotions and the acceptable or non-acceptable expression of emotions. The natural human tendency to dwell on negative thoughts and emotions feeds the idea that they are problematic, that we should not feel them, and that we need to make them disappear to function well.

The message that is commonly spread is that we can and should control our emotions, and we develop the belief that we can activate and deactivate our thoughts and emotions at will. This is what drives the fight against what we often call our negative thoughts and emotions.

Summarize that, generally, fighting and avoiding emotions brings us to suffer more in the long term. Bring the discussion back to the matrix from the previous week. Explore with him if this fight could be having the effect of digging with the shovel or of making him take fighting or avoidance actions, and therefore ending up stuck in a loop or a vicious circle (remind him of the week 2 session).

WEEK 3 — MAKE ROOM FOR OR STRUGGLE AGAINST

Experiencing the futility of trying to control thoughts and emotions—pink elephant:

- Therapeutic tool: Guide de la matrice ACT p. 106-107.
- First part—Ask the client to not think about a pink elephant for 40 seconds.

CONTROLLING THOUGHTS

How many times have you thought about a pink elephant in the past week?

Don't think about it for 40 seconds…

In your mind, did you often tell yourself: Don't think about it!!

How likely are you to succeed?

Most of the time, it comes out that people think about it despite the instruction not to do so. We then take a few minutes to realize that just because we want to stop thinking about something doesn't mean we will be able to.

Ask the question: How many times in a day do you tell yourself, don't think that?

Or, don't feel that?

CONTROLLING EMOTIONS (OPTIONAL)

Does your mind often tell you: Don't feel that?

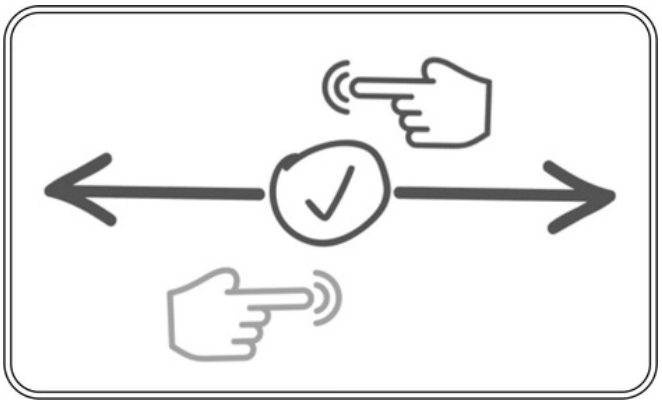
What chance do you have of succeeding?

WEEK 3 — MAKE ROOM FOR OR FIGHT AGAINST

4. Openness versus fighting with thoughts and emotions

Human life brings about numerous challenges, obstacles, and trials. These difficult emotions such as anger, fear, worry, helplessness and grief can obviously be experienced. Through time, we learn that it serves nothing to run away from our problems. We must confront them directly. And it's difficult. When we experience a difficult emotion, our first reflex is to want to escape it, to avoid it and make it disappear in all sorts of ways. Remember that we have already begun to discuss this. Using (or other types of behaviours) may be a behaviour adopted over time to temporarily diminish your discomfort. The reality is that we cannot make a thought, an emotion, or a physical sensation disappear by controlling it with our will in the moment. In fact, often enough, the more we try to eliminate a thought, a memory, an emotion, the more this thought, memory or emotion takes space...Unlike a computer, we don't have a delete key...Our brain is not suppressive but rather additive.

Explain the two following rules:



If you like it, think about it and you will be able to get rid of it.

If you are seeking to get rid of it, you are stuck with it!

It seems that there are different rules for the real world (the one that we perceive with our 5 senses) and the world of our inner experience (the one with our thoughts and emotions).

In the real world (our senses), the rule seems to be:

- If you don't like something, think about it for a long time and you will eventually end up ridding yourself of it or controlling it.

In the world of our inner experience, it seems rather:

- The more you try to make disappear or control what you don't want to think or feel, the more you are "stuck" or trapped with it!

That's probably how we find ourselves stuck in loops or vicious circles, by trying to apply a rule that works in the outer world to our internal world...

Propose to the client that they observe how they behave in their daily life in response to the thoughts and actions that present themselves. Does he tell himself: Don't think about it! Don't feel that!

WEEK 3 — MAKE ROOM FOR OR FIGHT AGAINST

So, what do we do?
Recent research in psychology suggests that noticing our internal states (thoughts, emotions, physical sensations), without judging them or clinging to them, without desperately trying to make them disappear, helps us to deal with difficult feelings.

Even better, it is possible to train ourselves to welcome them, make room for them, accept that they are part of the human condition, to accompany ourselves in these moments to favour our wellbeing.

Here is one of the methods to deal with the emotions that present themselves to us:

The five stages of acceptance:
Acceptance consists of stopping the fight against our personal inner experiences. Our thoughts, our feelings, our memories, etc. It does NOT mean passively accepting our life situation or wallowing in self-pity. Just the opposite, it is an ACTIVE process that aims to better deal with everything that can present itself in human life, to adapt to it better.

Openess to or fighting against our emotions		
Stages	**What is it?**	**How to do it**
1. Resisting	Fighting against what presents itself. It is the first reflex that often presents itself.	• Ignore, deny what is present. • Distraction. • Avoidance (including using).
2. Recognizing	Turning towards discomfort, towards what is felt inside with curiosity.	• Ask yourself: what do I feel?
3. Allowing	Tolerating, in full security. Holding on. I don't like this, but I can live it. Bearing it for now.	• Allow the emotion to exist, by reminding yourself that our emotional states are moments with a beginning and an end and that they will not last forever. • Locate the emotion in the body: what are the physical sensations associated with an emotion in the moment.
4. Welcoming	Letting feelings come and go. It's ok, I can make room for this.	• First take a few slow and deep breathes, let the sensation take more space, amplify the sensation.
5. Adapting	Seeing the value in difficult emotional experiences. What can I learn from this? How can I advance with what is presenting itself?	• Decide how you want to respond to this emotion that you feel • How can you acquire wisdom from this emotion? • Explore what the emotion is trying to communicate: what is important to you. About what is truly meaningful to you. About what type of person you want to be. About what you really want. What should you do more, less, or differently. What do you need?

What you resist, persists. What you embrace, dissolves. –Carl Jung

WEEK 3 — MAKE ROOM FOR OR FIGHT AGAINST

5. Emotions and high-risk situations

Engage the client in a discussion/reflection about emotions associated with high-risk situations and on the emotions that generally precede the use of substances. The client may talk about emotions that they want to avoid or reduce (e.g. anger, sadness, boredom) and emotions or desires that they want to reinforce (excitation, happiness, sexual excitement).

Possible script:

“We will do an exercise to learn new ways to deal with emotions.” Some of these exercises might be difficult, so take a moment to reflect on what motivates you to be here and on what this exercise will help you to do.

Once you are ready, think of a high-risk situation or an emotion that increases the possibility that you will consume alcohol or drugs.

Notice what you think and feel in this situation.

See if you can name what presents itself to you in this moment (pause 5 seconds) (thoughts, emotions, behaviours). This if the RECOGNIZE part (2).

Bring attention to the part of your body where this emotion or feeling is found: stomach, throat, chest, or no specific area.

If you can ALLOW (3) this feeling to be there. You do not have to like it or want it, just let it be...because it is anyways! Changing or getting rid of this feeling is not the goal. Like the weather, these emotions or sensations are there for a time, and they will make way for different weather at another time.

If you want, do a light massage on the area expressing the emotion. You can also take a few slow, deep breathes. If you want, allow yourself to say supportive and soothing words WELCOME (4).

And now, what learning or knowledge or wisdom could be hidden behind what is present? What could this tell about what is important for me and the person that I want to be? How do I want to act? What do I want to do? ADAPT (5).

Discussion: engage in a discussion with the client and ask him to share his reflections on the activity. Clients may have different responses: certain ones can say that the emotion is reduced or was displaced, others that it stayed the same, others that it increased. None of that is bad! The idea here is to:

- Perceive felt emotions in a less negative or threatening way
- Explore the idea of responding in a different way than we usually do
- Learn that, no matter the difficulty or emotion, we are “bigger” than it and we can learn to welcome it

Show that the process can allow us to not automatically take the shovel and start digging, or to engage in a vicious circle or stuck loop.
The ladder is there!

6. Emotions and high risk situations

Give a reminder to do the exercise at home

7. Verification:

What is the thing that you’ve retained from today’s session?

Session adapted from:

Polk, K., Schoendorf, B. Webster, M. & Olaz, F. (2017). Guide de la matrice ACT. Deboeck ; Belgique.
Harris, R. (2019). ACT Made Simple. 2nd edition.
Neff, K., & Germer, G. (2018). The Mindful Self-Compassion Workbook: A proven way to accept yourself, build inner strength, and thrive.

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WEEK 4

Urge surfing

WEEK 4 — URGE SURFING

Objective

✓ Develop competencies to get out of autopilot.

✓ Introduce competencies/strategies to manage urges to use.

Material

Documents to provide:

- Urges “Moments of Choice”
- Exercise : S.O.B.E.R. breathing space

Self-observation journal

1. **Mindfulness and verification (around 3 minutes)**

2. **Revision of exercises from the last session**

   Review the concepts discussed.

3. **Autopilot metaphor**

   I would like to present to you the idea that we, as humans, often function in “autopilot mode.”

   “Imagine that you are a ship with an autopilot option. If you have a tendency to navigate in the same waters, from one port to another, it is more logical to activate autopilot mode. This means that we can concentrate less on navigation and driving and busy ourselves with other things. If we regularly navigate these seas, the autopilot may become the default mode of the ship. The autopilot is excellent as long as the ship is going in the right direction.

   Our mind is like an autopilot. Our mind allows us to carry out all sorts of complicated actions without having to think about them. In fact, if we didn’t have this ability, life would be much more difficult. For example, think of all the things that you’ve had to do to get here today, and think about how much time this would have taken you if you had had to think about about each of those things. This capacity is very useful for conserving our energy and accomplishing what we need to do in a day.

   Let’s come back to the ship. If the ship is in autopilot and it is heading towards rocks, the fact that autopilot is activated becomes a problem. The captain needs to know that the ship is heading towards the rocks in order to disengage autopilot mode, in order to take the helm and change course.

   I would like for us to remember that we are the captain of our own ship. Even if we sometimes have the impression that our mind that is in charge, as the captain, we have the ability to notice when we are going the wrong way and to take measures to get us back in phase with what we want.”

4. **Relationship between autopilot and the urge to drink**

   Our mind goes into autopilot for behaviours that are repeated and that can become habits, like using substances.

   For autopilot to work, the following conditions need to be met:

   - Routine cues or triggers or habits learned through reinforcement or reward.
   - When we are in autopilot, we act without thinking about what we are doing. In many ways, we are in autopilot when we use substances. The fact that we are in autopilot also increases the risk of using substances.

   What are urges or cravings?

   The psychological state of craving is the anticipation or the desire to have the effect of substance.

   Cues or triggers: internal or external stimuli that triggers a craving or a strong urge.

WEEK 4 — URGE SURFING

Implicit habitual behaviours:
Thoughts concerning the potential positive effects of substances. Thoughts concerning the delay of gratification felt as aversive. Seeking substances in a compulsive manner.

Manifested habitual behaviours:
Substance seeking; substance use.

Reinforcement: effect of substances
Being in autopilot increases the risk of substance use or relapse.

5. Urges and the moment of choice: session activities

Remember a moment, which could be recent, where you had an urge to use. For the purpose of this practice, don't choose one of the most difficult situations, but something that was of a light or medium intensity. Once this situation is very present in your mind, think of what follows: follow the path as presented in the table. Don't forget to adopt a curious attitude without judgment towards what you are living.

Orient the client towards the reference document "Moments of choice" concerning cravings and impulses. Review the document and respond to the questions that are asked.

EMPTY TABLE ON THE MOMENTS OF CHOICE TO BE FILLED DURING THE SESSION (refer to the matrix and the hooks).

6. Managing cravings

Cravings are often the hardest part of recovery. It is very common to have unpleasant and difficult thoughts about cravings. It is important to remember that cravings are a normal part of recovery.

Remember:
Cravings to use are experiences that are limited in time. Even though, while we are going through the craving, we may have the impression that our mind is telling us "this will last forever" or "this will only go away if I use," cravings increase in intensity, but always eventually disappear.

To manage cravings, we need to:

- be aware that they are present
- remind ourselves that they are limited in time
- accept, recognize and manage cravings that are hard to manage

Strategies:

1. Urge surfing:

Instead of fighting craving, you accept that the craving comes and goes and you experience this craving passing through your consciousness. When you feel the urge to use, imagine that it's like riding a surfboard on a wave, the urge being the wave. The wave rises and falls and finishes by dissipating, because it is not permanent, like all the rest.

Regularly verify your state to evaluate your craving on a scale of 0 to 10. Breathe into the urge, make room for it, allow it to be there. Study it like a curious scientist. You can make entries on a paper in intervals of five or ten minutes, while evaluating the intensity of your craving on a scale of 0 to 10.

WEEK 4 — URGE SURFING

2. **Take a moment to suggest other strategies** (e.g. calling a friend, starting a pleasant activity, leaving the room, imagining a scenario of drinking all the way to the end (with the guilt, shame, regret, etc., that often follows, delaying the moment of use, etc.), taking a shower, eating something, doing an acceptance exercise or expression within the context of this therapy)

   The following activity can be explained and practiced (if time allows) at this stage of the session:

3. **SOBER breathing space**
   This is a mindfulness competency that encourages clients to notice and get out of autopilot when they find themselves in a high risk situation or if they are triggered.

   Explain the following steps:

   S — Stop: The first step, when you are in a stressful situation or at risk, consists of slowing down, stopping yourself, taking a moment to get out of autopilot.

   O — Observe: Observe what comes up in terms of sensations, emotions, thoughts and urges. Describe what presents itself to you, e.g. “I have the thought that...”, “I notice the emotion of...”

   B — Breathe: Bring attention to your breathing for a few moments.

   E — Evaluate: Widen your consciousness to take the perspective of an observer. Note what is happening for you in this moment, in this particular situation.

   R — Respond (versus reacting): Respond to what is present and bring your attention to what is important to you. You always have a choice in what you do and in how you respond.

4. **Encourage the client to fill in the “SOBER breathing space” followup during the week.**
   It consists of a mindfulness skill that encourages the client to notice and get out of autopilot when they find themselves in a high risk situation or when they are triggered.

5. **Verify what they retain from the session.**
   Briefly, if time permits, go over some relapse prevention elements, such as recognizing triggers, and how to manage them or reduce them and how to create favourable conditions in advance (avoidance of places linked to use or people who use, life hygiene, etc.)

Session adapted from:

Polk, K., Schoendorf, B. Webster, M. & Olaz, F. (2017). Guide de la matrice ACT. Deboeck; Belgique. Chen,

P. et al. (s.d.). Mindfulness Based Relapse Prevention for Problem Gambling. Récupéré sur : https :// www.greo.ca/en/greo-resource/resources/Documents/mindfulness/mindfulness-manual_CC-license.pdf

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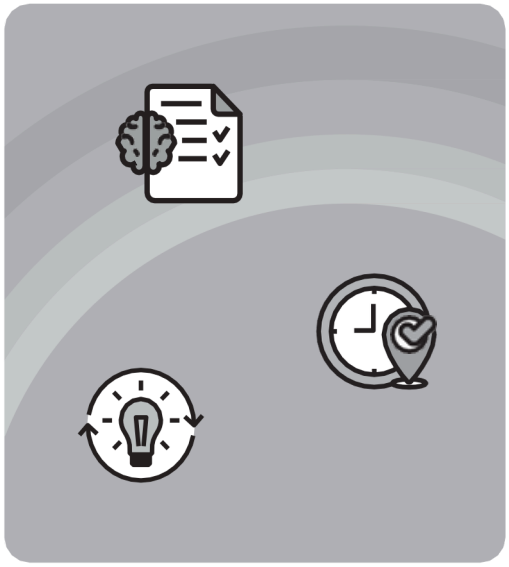


WEEK 5

Reactivating my life

WEEK 5 — Reactivating my life

Objective

✓ Discuss the concept of activation.

✓ Discuss the motors of change.

✓ Help clients to identify experiential avoidance (running away, obstacles) of experiences.

Material

Documents to use and/or give to the client:

- Observation journal (exercise).

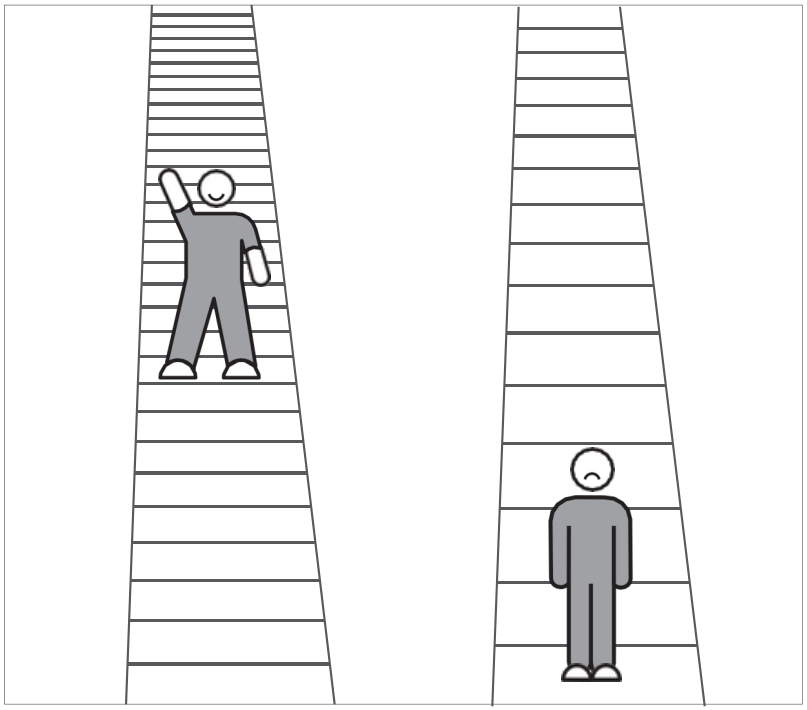
Notes/instructions for the therapist

1. **Start by a brief mindfulness exercise** (around 3 minutes of breathing)
2. **Look back on the week (craving and use of substances, etc.) and on the things they've learned in the preceding session in addition to the exercises.**
3. **Cover the seven forces of change:**

   Ladders:

   This concept emphasizes **breaking objectives down into steps that are smaller and more obtainable.** Each step reinforces confidence and momentum, therefore facilitating the maintenance of progress through time. There is no action too small when it goes in the desired direction of advancement. Often, a small action triggers the initial movement, which can encourage us to keep going and to continue.

The
Importance
of
small steps!



WEEK 5 — Reactivating my life

Community:
The support of a group, a network, or a person is crucial for maintaining motivation. Being part of a community can provide responsibility (responsibilization), encouragement and shared experiences that reinforce commitment to change and that help when going through inevitable moments of greater difficulty. Numerous groups exist, either in-person or virtually. Each person can, at different times, be the one who is helped and the one who helps. To feel truly understood and recognized by people who have been through, or who are still going through, difficult periods is important for all humans.

Important:
Understand why change is important for you personally can help to reinforce your determination. Linking changing to what is important in your long-term goals can make it more significant.

Easy:

Making changes as simple and realizable as possible can increase the probability of success. Reducing barriers and creating an environment that facilitates desired behaviours helps to establish new habits.

Mental strategy:
These are strategies based on neuroscience that take advantage of the way our brains work to favour change. Techniques such as visual aids or positive reinforcement can improve motivation and the retention of new behaviours.

Captivating—pleasurable:
Being interested and emotionally involved makes the process of change more pleasant. Finding ways to render the experience more pleasant or gratifying can help to maintain motivation.

Rooting:
This refers to the process of integrating new habits in your routine until they become automatic. **Consistency and repetition** are essential for making behaviours automatic through time.

4. **Talking about the concept of activation:**
   When people find themselves in your situation, many people stop or take fewer actions to take care of themselves, their health, and their well-being.
   When we stop taking care of ourselves, of our bodies, of our hearts, of our brains, our lives can become more depressing. We may, in the moment, have the feeling that we are comforting ourselves by stopping the things that we don't feel like doing anymore or that we are not motivated to do, but it might be that this inactivity, this withdrawal, this isolation worsens or maintains our difficulties.
   We often have a tendency to wait to want to act, to move, or think that, if we don't feel like it, we have to act in that direction. The act of waiting or putting off doing things that are good or useful for the self, again and again, makes us even less likely to recover. Motivation does not come before, but follows, with time, the actions that you engage in. The goal is to start moving again gradually even if you don't want to.
   We often talk in this life of *activating or reactivating an account, a password, a connection, a link...to have access to something*...this is what we propose to you; activating or reactivating gestures, actions to have access to something else...

WEEK 5 — Reactivating my life

Here are the steps for REACTIVATING YOUR LIFE

STEP 1: WHAT ACTIVITIES COULD I do to ACTIVATE or REACTIVATE my life?

Past activities that were **enjoyable, pleasant, enriching**

Activities aimed at **reducing use** or **generating life conditions that are incompatible with use**

Activities related to **life hygiene**

- **Personal care**, hygiene
- **Eating** to nourish our bodies and minds
- **Activity: moving**
- **Daily tasks and responsibilities**
- Activities that keep us **connected to others** (e.g. family, friends, colleagues)
- etc.

STEP 2: CHOOSE TWO ACTIVITIES that will be the easiest to do right now
STEP 3: ESTABLISH OBJECTIVES by considering the forces of change previously discussed
STEP 4: ACCOMPLISH YOUR OBJECTIVES
STEP 5: RE-EXAMINE YOUR OBJECTIVES

5. Discuss your psychological obstacles:

According to the FEAR acronym (Fusion, evaluation of experience, avoidance of experience, reason-giving for behaviour).

Fusion with your thoughts: Identifying with negative thoughts that block action and believing that thoughts are reality.

Evaluation of experience: Setting goals that are not realistic given the available ressources.

Avoidance of experience: Unwillingness to feel uncomfortable emotions linked to change (remember that change is difficult and getting out of your comfort zone (or known discomfort) is inevitable).

Reason-giving for behaviour: Losing sight of what is important, the real reasons why we might do things differently or that might cause us momentary discomfort.

• What are the possible internal difficulties (difficult thoughts and feelings like poor motivation, doubt, distress, anger, despair, insecurity, anxiety, etc.)?

• What are the external difficulties, factors in the environment (things other than thoughts and feelings that could stop you, such as lack of money, lack of time, lack of skill, personal conflict with other people involved)?

WEEK 5 — Reactivating my life

How to overcome obstacles:

The antidote to FEAR is DARE (Defusion, Acceptance of Discomfort, Realistic Goals, Engage in what is Important):

Defusion: identify and distance oneself from limiting thoughts:

• Acceptance of discomfort: Welcome difficult emotions in order to advance, recognize that they are part of the equation and they don't have to dictate what we want or can do or what we don't want or cannot do. Emphasize that negative emotions, just like positive emotions, come, go, and come back.

• Realistic objectives: Adjust objectives as a function of resources, either by gaining new competencies, or by accepting one's limits.

• Engage in what is important to me:
Reflect on the significance of actions to maintain motivation.

6. Session summary:

Present the exercise of the week:

Choose a behaviour/action that you want to do this week, e.g. go take a walk, drink less liquor, eat fewer chips, etc., and make it happen using the seven forces of change, all while breaking it down into more manageable steps.

Ladders: This concept emphasizes breaking objectives into smaller and more obtainable steps. Every step builds confidence and momentum, therefore facilitating the maintenance of the progress through time.

Community: The support of a group or network is crucial for maintaining motivation. Being part of a community can confer responsibility, encouragement and shared experiences that reinforce your commitment to change.

Important: Understanding why change is important for you can reinforce your determination. Linking change to what is important and to your long term goals makes it more significant.

Easy: Making changes as simple as possible can increase the probability of success. Reducing the barriers and creating an environment that facilitates the desired behaviours helps to establish new habits.

Mental strategies: These are strategies based in neuroscience that come from the way our brain functions to facilitate change. Changes such as visual reminders or positive reinforcement can improve motivation and the retention of new behaviours.

Captivating—pleasurable: Engaging your interests and your emotions renders the process of change more enjoyable. Finding methods to render the experience exciting or gratifying can help maintain motivation.

Root: This refers to the process of integrating new habits into your routine until they have become automatic. Consistency and repetition are essential to render habits automatic through time.

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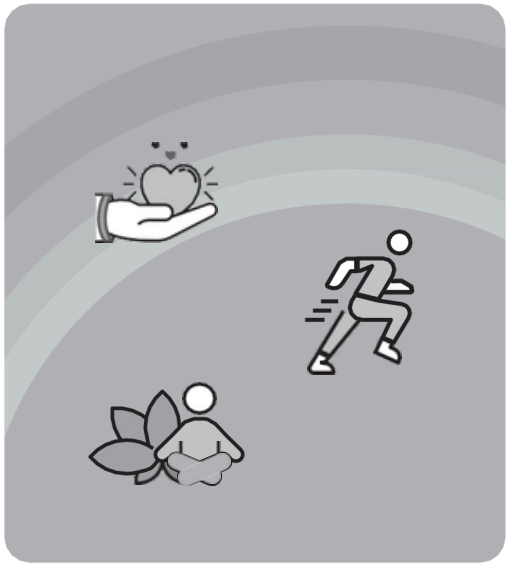


WEEK 6

Committing to what is truly important for me

WEEK 6 — Committing to what is truly important for me

Objectives

✓ Defining values, or what is important in life, and how that affects our behaviours.

✓ Carry out a reflective activity on what is important and how to take committed action as a function of values with the Bull's-eye exercise.

✓ Make the link with the right part of the matrix (values and committed actions).

Material

Documents to use and/or give to the client:

- Clarify what is important (Bull's-eye exercise).
- Self-observation (exercise).

1. **Start with a brief mindfulness exercise** (example, 3 minutes of breathing, etc.)

2. **Review the week, substance use, craving, etc., and return on the subject of the previous week.**

3. **Discussion: What are the values? Where to use the concept of important things/people/qualities/characteristics in your life (what is important for me?)**

   Metaphor: Values are like a compass. They guide us in the direction we want to follow. They give purpose to our lives. They are embodied, taking life in the gestures, actions, the behaviours that we carry out:

   - Values are the way that you want to behave openly and secretly in different situations and contexts.
   - Values are related to people and things that matter to you. Embodying them, even if it is not always easy, often gives the feeling of being in your element, of being happy with yourself.
   - Values are here and now. We can live according to our values in the present moment.
   - Values don't all have the same importance. Some may be more important for you than others.
   - It is best to take our values lightly: we want to be conscious of our values and use them to guide us, without becoming rigid and getting stuck.
   - Values are freely chosen.
   .
   - Distinguish values from objectives.

WEEK 6 — Committment to what is truly important to me

4. **Activity: Detailed worksheet consisting of the Bull's-eye and making the link with the matrix**
5. Revisit the obstacles that can appear (left part of the matrix), FEAR and strategies that can be used (DARE).
6. Identify 1 or 2 committed actions as a function of values (with or without the exercise of making the life that I want grow–tree) and possible obstacles.

   Perspective-taking exercise starting from an action chosen at a precise moment:

   Guide for the perspective-taking exercise

   Ask the client to choose a planned action at a precise moment and context. Ask him to teleport to the precise day and moment. Ask him how he is there, in that moment, with regard to the action chosen.

   Begin to establish a dialogue between the client HERE NOW and the client THERE (say his first name).

   For example, invite the client to say something helpful to (say his first name). Then ask how (say his first name) receives the message. Is there something that he wants to answer? Encourage this dialogue between the client here and the client over there. If needed, after having asked permission, you can invite the client to validate the perspective of the client over there (e.g. yes, it is not easy to...) or invite him to say something that could be encouraging (e.g.: It's true, it's hard to start, you will probably be happy to have done it in X minutes). If you observe flexibility, ask what (say his first name) will do next...Ask, in ending, how it was to have this type of exchange. Finally, ask the client to estimate the probability that they will encounter _____ to have this type of exchange when he will be in that situation.

7. **Discuss next week's exercise**

   Based on the session activity, ask the client to practice the exercise of the week:
   Name 2 or 3 values that you would want to put in place throughout the day. What are the 2 or 3 things that you want to embody that day. Try to integrate these values in your day.

   CAUTION :
   Identify the obstacles that prevent the client from practicing these values (from embodying his values or acting in their direction–proposed idea), and work with them to find ways to overcome these obstacles in order to increase their chances of success during the week.

   Encourage clients to practice daily. Encourage clients to fill in the "Observation Journal" between sessions.

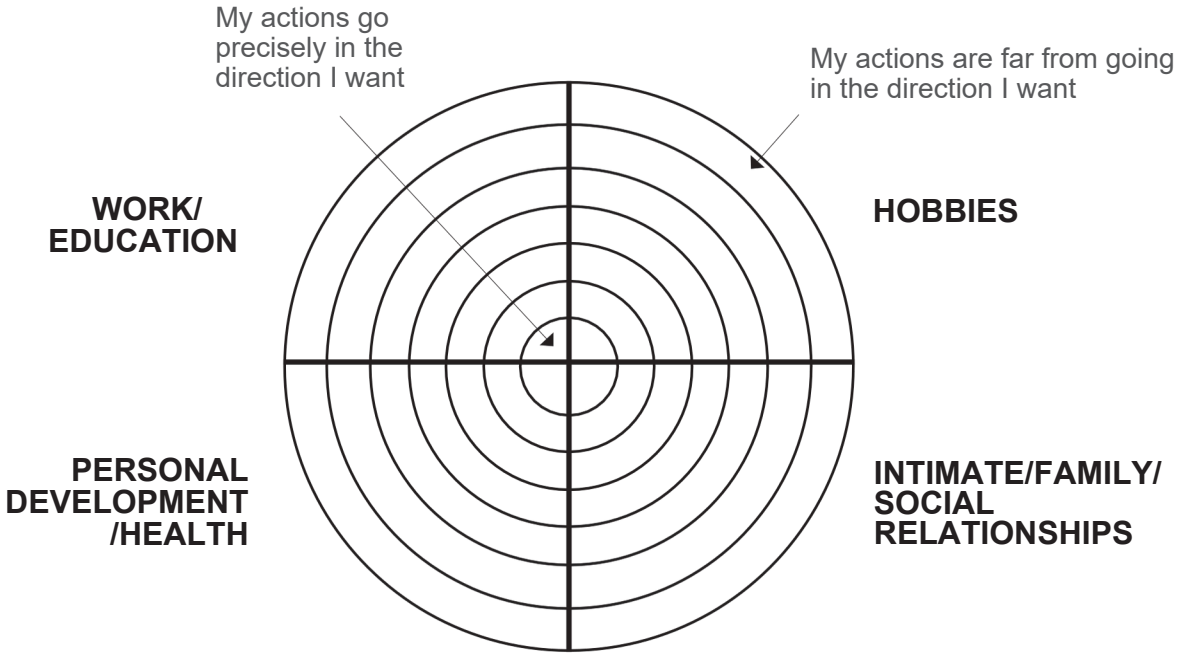
8. **Verification**

   What have you retained from today's session?

WEEK 6 — Committing to what is truly important to me

Bull's-eye: value-driven actions

On the target below, mark down with an X to what extent your actions throughout the past week went in the direction of what is important for you, in each of the four big domains of life.



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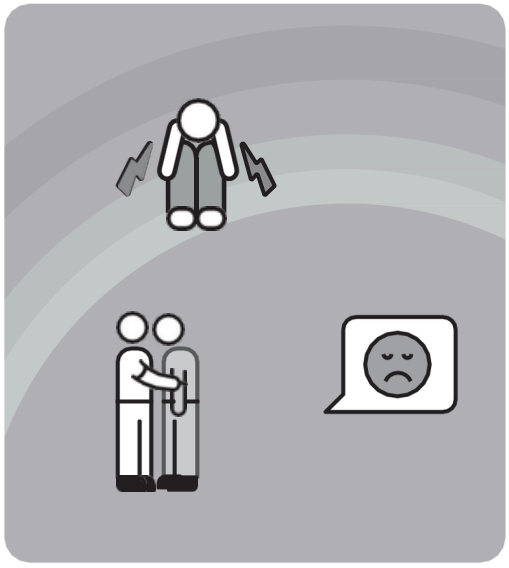


WEEK 7

Shame

WEEK 7 — SHAME

Objective

✓ Define shame.

✓ Help the client to identify his shame-related behaviour profile and behaviours

Material

Home-based exercise: Explore shame.

David Goudreault video (lettre d'amour aux alcooliques)

1. **Mindfulness exercise and review of the past week and exercises.**
2. **Present the David G. video and discuss.**
3. **Understand shame and guilt:**

   Shame is a complex emotion that is an integral part of our human experience. It is often triggered by situations where we feel judged or exposed, and it can bring us to distance ourselves from who we are. Contrary to guilt, which is focused on specific actions, shame touches our very identity. Shame is nearly always devastating, particularly in contexts where expectations are not realistic. In some cultures, shame can surge when we don't meet familial expectations. In others, it can come from the inability to meet our own standards.

   Use the video.

4. **Shame-related thoughts:**

   Shame-related thoughts can show up in different forms, going from self-accusations to negative comparisons with others. For example:

   - Self-deprecation: "I'm not good enough."
   - Social comparison: "Everyone is more successful than me."
   - Negative anticipation: "Others will judge me if I do that."

   These thoughts can become recurring schemas, creating a cycle that is difficult to break.

5. **Body sensations:**

   Shame is often accompanied by intense physical sensations:
   Physical discomfort: you may feel abdominal pain, muscular tension, or heat sensations.

   Stress reaction: shame activates the stress response, increases heart rate and makes breathing more rapid.

   Closed posture: we have a tendency to adopt postures that reflect our emotional state, like crossing our arms or lowering our head.

6. **Reactions when faced with shame:**

   When faced with shame, several reactions can occur:
   Avoidance: removing oneself from social situations or avoiding interactions, escaping with actions that are likely to be damaging in order to numb oneself, not feeling anymore or being less in contact with what is felt.
   Another form of avoidance is to not take responsibility, to blame others, therefore justifying that we don't have to do the part of the road that belongs to us.

   Confrontation: trying to overcompensate with dominant or agressive behaviours.

   Approval seeking: bending to the will of others to avoid judgment.

   These reactions can bring about a distortion in our self-image and superficial relationships.

WEEK 7 — SHAME

These mechanisms distance us from our authenticity, from a part of ourselves and our ability to have deep bonds with others.

WEEK 7 — SHAME

7. **Personal reflection:**

   Take time to reflect on your experiences with shame.

   Here are a few questions for that reflection:

   - Think of a moment where you listened to your shame. What did you experience?
   - Think of a moment where this emotion impaired your functioning, your relationships: what consequences did it have on you and your interactions?

8. **Using shame or guilt:**

   Shame or guilt require that we take a moment to understand them. When we feel shame or guilt, instead of reacting to avoid or eliminate them, it is more useful to recognize the emotions and to explore their roots. This takes a certain amount of courage that we believe you are capable of.

   - It requires humility and courage to recognize what could have or can make us feel guilty (behaviours that we have done) or shameful (judgment about our person).
   - At one point in life, we may want to become aware of these emotions to advance our lives. Some talk about taming their shadow, others of looking their experiences in the face to turn them into learning experiences, others of taking responsibility but without demonizing themselves...
   - Some eventually choose, when the time is right, to carry out reparations, to make honorable amends, to apologize to people who they may have hurt with certain behaviours.

   Self-help groups are often helpful for these types of steps. They help people to not feel alone and isolated in this experience with powerful feelings, by realizing that others have lived or live with the same type of journey, in realizing that we can make reparations with both ourselves and others, that we are not only the actions that we have taken...

WEEK 7 — SHAME

Reflective activity: my shame profile or taming my dark side.

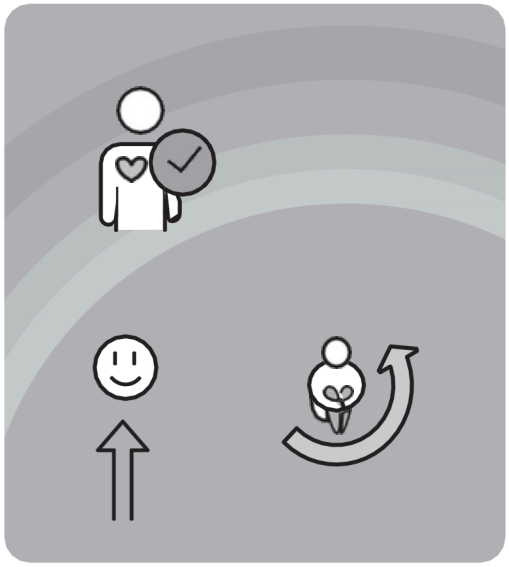
Moving from shame to guilt	
What are the situations or events that trigger shame?	
Notice your thoughts when you feel shame. What physical sensations do you feel when you feel shame? What is your posture or body language when you feel shame?	
Describe situations where you avoid your shame.	
Think of a moment where you listened to your shame. What did you experience?	

Verify with the client what they retained from the session.

Exercise to do at home:

To deepen your reflection on shame and guilt, use the worksheet provided. Choose an experience related to shame and explore it instead of running away from it to see if it is possible to learn something from it.

An evolving, patient-adapted acceptance and commitment therapy



WEEK 8

Compassion

WEEK 8 — COMPASSION

Session plan

✓ Start with a mindfulness exercise
✓ Review exercises from the past week about shame and review last week's exercise about craving
✓ Video by David Goudreault (if needed, present a second time).
✓ Psychoeducation on self-compassion.
✓ Practice and teaching on the self-compassion pause with K. Neff's three components.
✓ Plan exercise of the week.
✓ Relapse prevention.

Objectives

✓ Sensitize the participant to self-compassion as a tool to be there for themselves in difficult moments.

1. Outline of the session

✓ Review of the video (lettre d'amour aux alcooliques David Goudreault).

✓ Then ask one or multiple of the following questions to bring out one or more experiences of the client.

✓ Examples of questions from the therapist:

- How did you find this letter—video ? How do you take it?
- Do you see yourself in this letter—video? If yes, in what way?
- Are there things that you have already told yourself or that you have already done that are not easy to recognize?
- Have you ever felt embarrassed, discouraged, rejected, shameful, guilty, angry, alone, in the face of what you have already experienced or might still be experiencing?

Welcome with openness kindness what the client might deliver and mention that thousands of people (like you, if it's the case), currently recognize themselves and will recognize themselves in the future when listening to this video. Why? Because it was written by someone who experienced it and still lives with it because it touches the experience of most people living the same situation.

✓ Psychoeducation: remind them that problems of addiction and depression often put our view of ourselves and our lives under great strain. Difficult moments, often very difficult, are frequently lived by the people who are facing them. Severe self-judgments, devalorization, a feeling of powerlessness, isolation, discouragement, shame...are part of what can be felt.

Mention that our way of being there for ourselves, supporting ourselves personally when we are going through these tumultuous periods, have a considerable impact on our psychological state.

What do we really need in these moments?

Banging our heads, devaluing ourselves, denigrating ourselves, self-flagellation...? Are they really necessary or useful for getting through these periods? Is there a method to get through these difficult moments in a more tender and gentler way, without calling ourselves all kinds of names, all while assuming responsibility and reaffirming or pursuing our commitment towards a desired path?

WEEK 8 — COMPASSION

Mention that science on compassion and self-compassion suggests yes! Research shows that self-compassion can bring about numerous benefits for those that integrate it into their lives.

- Better adaptation to all kinds of situations.
- Improved life habits.
- Improved motivation to learn, improve, and persist in effort.
- Taking accountability for one's behaviour.
- Improving relationships with others.
- Reducing difficult mental states—anxiety, depression, stress, shame, perfectionism.
- Increasing positive mental states—life satisfaction, connection, self-confidence, optimism, gratitude.

Compassion is the ability to compassionately welcome the suffering of others. Self-compassion is doing the same thing for oneself, to make space for suffering all while hoping to lessen it. It's staying available and present for what we feel, all while helping ourselves soothe what we are experiencing. It is a way to enter into friendship with oneself, of reconciling with oneself.

Then, present self-compassion with its three components (with the Germer gestures that are associated with each component–type Youtube Christopher Germer on Mindful Self Compassion–February 1st, 2019, at time 25:00 to 28:30 for demonstration), that you will practice in the session with the client.

Our first reaction when faced with obstacles is often to tense up and stiffen. It is the initial stress reaction to fight or take flight. Tighten your fists, your jaw and your body. Ask the client to do it at the same time if he wants.

Self compassion is:

- Open your hands, elbows against your body. Ask the client to do the same. Present the first component, a state of openness, of welcoming, of receptiveness.
- Then do a circle in front of you with your arms, shoulders lowered.
- Present the second part: I am not alone, I am connected to other humans who, like me, go through difficult things.
- Gently place your hands on your heart or at the centre of your chest. Present the third component: an intention of kindness, tender and gentle with yourself.
- Go over again, with a bit more detail, the three components while explaining and giving examples.

Three components of self-compassion:

1. **Attentive presence or mindfulness**

   We cultivate, from the beginning, a state of openness, of receptivity, of non-judgment allowing us to observe our thoughts and emotions as they are, as they present themselves without trying to erase them or fighting against them. We cannot ignore or stop caring about our suffering and, at the same time, feel compassion and kindness towards ourselves. We turn towards what we feel instead of pushing it away.

WEEK 8 — COMPASSION

2. **Shared common humanity**
   We then recognize that suffering and imperfection are part of our human condition. It is shared by all humans on our planet. It is something that we all feel at one moment or another in our lives; it is part of the human experience. It is not a thing that only happens to me. I am not alone...
3. **Kindness towards oneself**
   We then take care of the suffering when we hurt, when we live a failure or feel inadequate. Instead of ignoring or not caring about our suffering, or self-criticizing, denigrating, flagellating or crucifying, we show ourselves understanding for what we are living, warm, supportive, comforting and present. We seek to soothe ourselves, support ourselves in an active way because we are suffering and we need it. This can be through spoken words, gestures, or actions.

We can also explain that, when we criticize ourselves and judge ourselves, it activates a defence system in our body that produces cortisol and adrenaline. Self-compassion, on the other hand, activates the caring system that is associated with the production of oxytocin and endorphins (natural opioids).

Guide the participants through the K. Neff self-compassion pause with the three components cited earlier (see the video from Christopher Germer on Mindful Self-Compassion–31:00 to 39:15 for a demonstration from K. Neff in English or in French. The self-compassion pause from CIUSSS de l'est-de-l'île-de-Montréal— 6:10-13:50 by Martine Vaillancourt) if you still have time.

Obtain feedback on this exercise.
In summary, self compassion is taking care of oneself, when we are suffering, the way we would for someone we love, who is important to us. It's becoming your best friend, a parent that doesn't leave you, a coach who is present in difficult moments as well as in the good moments. It's an active process where we serve our values and benefit ourselves and often our loved ones. Nothing to do with cowardice, self-pity, or ease.
Quite the opposite, it requires courage at first.

✓ Present the exercise of the week by asking them to observe their fighting reactions (tensing actions) or of welcoming with the three components (redo the gestures). Give back the observation sheet.
✓ End with feedback from the client on the session and what they take away from it, allow a brief therapeutic review of the eight sessions.

Relapse prevention. Review the lessons and tools used, etc. Prepare a relapse prevention plan.

References

- David Gaudreault video
- Christopher Germer video on Mindful Self-Compassion
- S'aimer : comment se réconcilier avec soi-même, Kristin Neff (2013)

WEEK 9 — QUALITATIVE INTERVIEW

THERAPY BOOKLET

Weeks 1 to 9

An evolving, patient-adapted acceptance and commitment therapy

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This document uses the masculine gender to denote all genders, in order to simplify the text.

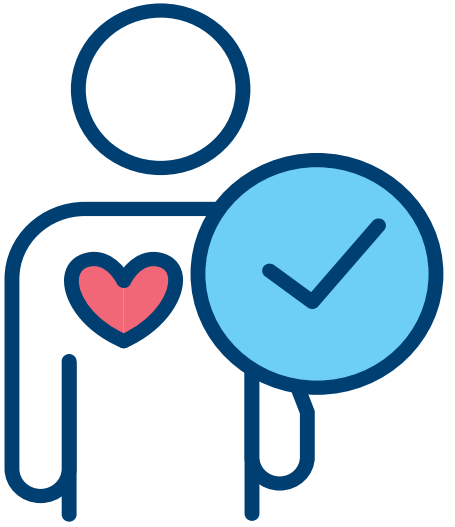
Table of Contents

ALEX'S STORY

Alex is 42 years old. He works in sales. For several months now, he has been going through a very difficult period. Depression has forced him to stop working and he feels lost. He describes his days as "an interminable emptiness," each minute being a battle against the urge to stay in bed. It is not the first time that he faces a depression, but this time, it's more intense. He has trouble getting up in the morning, being present for his loved ones, and finding pleasure in the things he used to enjoy.

For years, Alex has used alcohol as an escape. What in other times was an occasional drink has become a daily habit—five or six beers every evening to numb his emotions. When he thinks of his evenings, Alex feels a mix of relief and disgust. He feels very mad at himself about this. "I am weak" he often tells himself. This shame, like a slow poison, only feeds his depression. At times, he thinks about getting help, but the fear of judgment stops him: "What will they think of me?"

One day, his family doctor, worried that he is going downhill, refers him to a psychiatrist who is specialized in addiction. He is offered an 8-week program combining a prescription of ketamine alongside Acceptance and Commitment Therapy (ACT). Alex hesitates. He is scared to fail, but he finally decides to try the program and tells himself "Maybe this is my last chance to get out of this."



An evolving, patient-adapted acceptance and commitment therapy

WEEK 1

I’m specifying the direction I want to take

WEEK 1 — I'M SPECIFYING THE DIRECTION I WANT TO TAKE

Exploring what matters

At the first session, Alex enters the room with a mix of anxiety and hope. The therapist, with a warm smile, invites him to talk about what brings him here. Hesitant, Alex begins to tell him "I feel blocked and I don't know what to do."

The therapist asks a simple, but disconcerting question: "What life would you like to build?" Alex remains silent for a moment. He had never asked himself this question. Finally, he murmurs: "I just want to stop feeling like a failure."

To help him clarify his aspirations and identify what really matters for him, Alex mentions his family, whom he has a tendency to avoid because of his shame, and his health that he would like to get back under control. More shyly, he talks about his guitar that he hasn't touched for years. Seeing these words on the paper, Alex feels a spark of hope. "Maybe these things aren't as out of reach as I thought."

The therapist proposes an exercise for next week: observe the moments where he acts in accordance with what matters to him and those where he is moving away from them. Leaving the session, Alex feels a small spark of hope. For the first time in a long time, he asks himself: "What if I can still change things?"

And you, what truly matters to you and how can you get closer to these people or these things this week?

WEEK 1 — I'M SPECIFYING THE DIRECTION I WANT TO TAKE

Objective

- I'm discovering my therapy.
- I'm specifying the direction I want to take and I'm starting the journey.

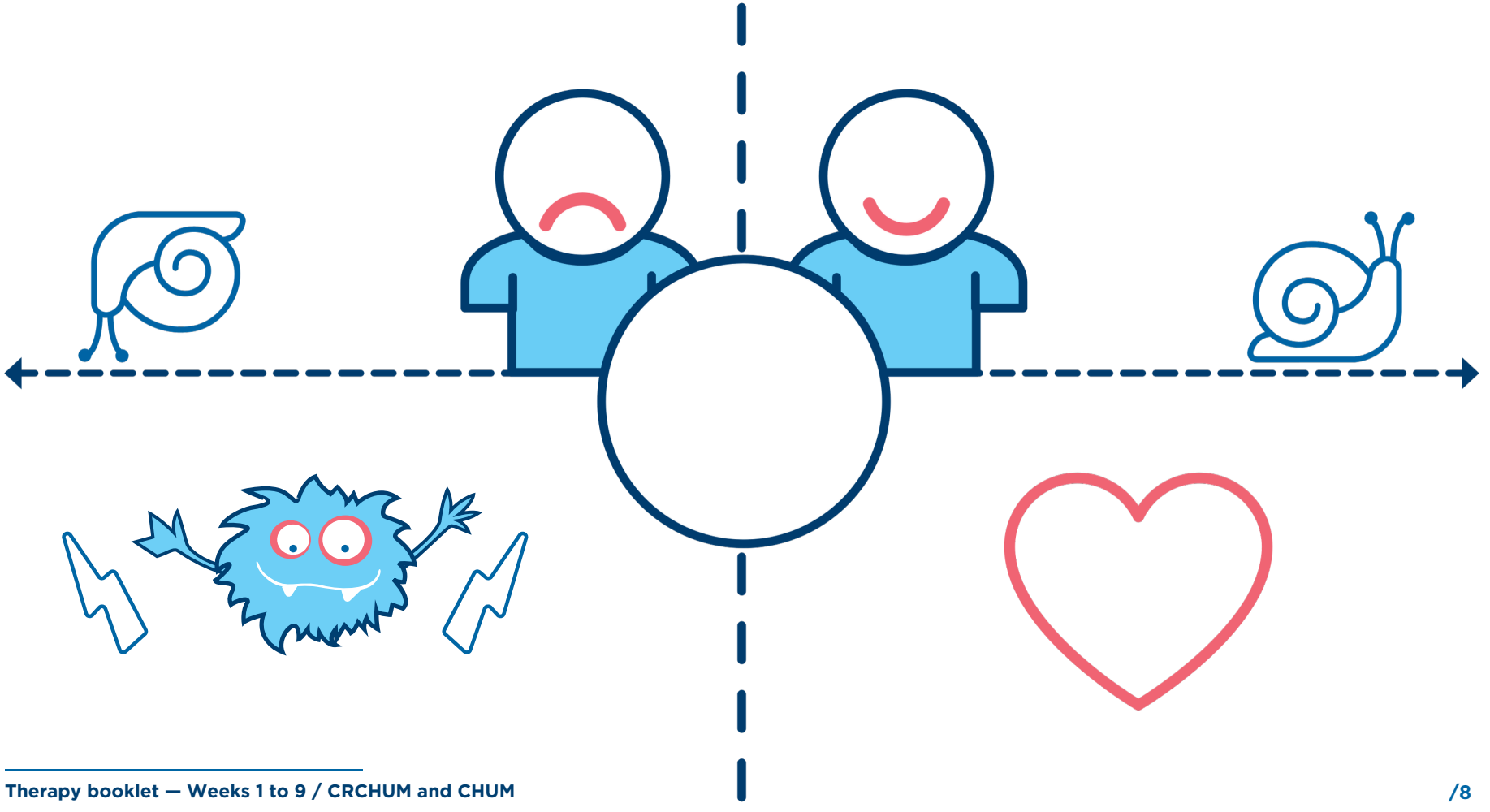
Concepts

- Identifying what is important to me (values).
- Recognizing the behaviours that bring me closer to my values (approach).
- Identify difficult thoughts and emotions that hold me back (inner obstacles).
- Distinguish my committed actions from my distancing behaviours (fighting actions).

Exercise

"I'm observing myself"

WEEK 1 — I'M SPECIFYING THE DIRECTION I WANT TO TAKE



WEEK 1 — I'M SPECIFYING THE DIRECTION I WANT TO TAKE

An evolving, patient-adapted acceptance and commitment therapy

WEEK 2

Why isn’t it working?

Distancing Behaviours

WEEK 2 — WHY ISN'T IT WORKING?
DISTANCING BEHAVIOURS

Recognizing your avoidance strategies

This week, Alex shows up seeming hesitant, almost nervous. He sits down gently and, after a long silence, he ends up saying "I noticed something..." His voice is marked by a slight hesitation. He continues, his eyes lowered "Every night, when I don't feel well, I go straight to the fridge to get a beer. At first, I tell myself that it will just help me get through the evening. But actually, I think it's become like a reflex."

He finally raises his eyes to the therapist, as though searching for validation or encouragement. The therapist nods gently, offering a safe space for Alex to continue. "And it scares me because, I know that it's not a good solution...but I don't know what else to do." The therapist nods his head and proposes a metaphor: "Imagine that you were in a hole, and each beer represented the strike of a shovel. Are you digging to escape, or are you sinking even deeper?"

Alex reflects. "I think I am sinking deeper." This realization is painful, but also liberating. He starts to see that his drinking habit is not a solution, but an attempt to run away.

Together, they explore alternatives. "What if, instead, you tried something else when you feel that need? Like playing the guitar or calling a friend?" Alex hesitates, but agrees to try out an alternative this week. He fixes himself a modest goal: replace one night with alcohol with a night playing the guitar.

When he leaves the session, Alex feels both nervous and determined. He tells himself: "Maybe I can do it differently, just this once, to see what happens".

And you, what are your ways of escaping and what could you try differently?

WEEK 2 — WHY ISN'T IT WORKING?
DISTANCING BEHAVIOURS

Objectives

Exploring why I avoid my difficult experiences.

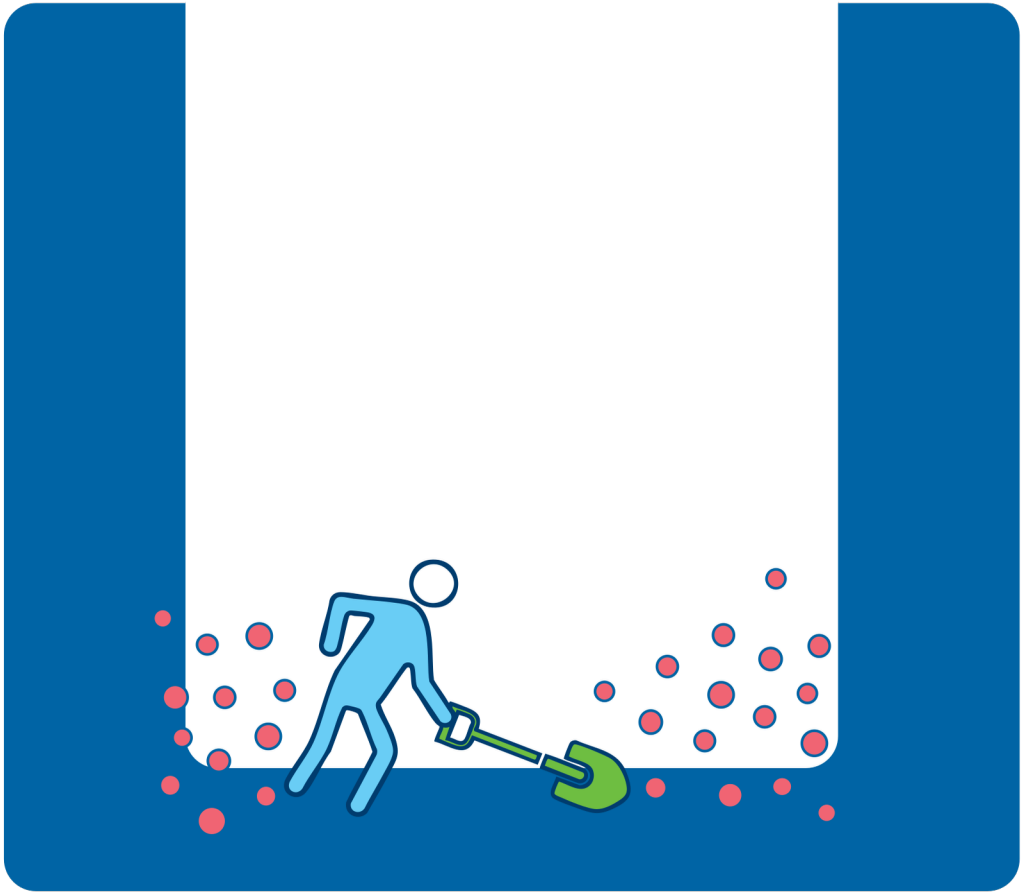
Concepts

- Identifying my triggers.
- Exploring my avoidance strategies (distraction, escaping) and their short and long-term consequences.
- Learning to recognize and accept my thoughts and emotions instead of fighting against them.

Exercise

"I'm discovering"

WEEK 2 — WHY ISN'T IT WORKING?
STRATEGIES



WEEK 2 — WHY ISN'T IT WORKING?
DISTANCING BEHAVIOURS

Observation journal

During the next week, notice in what situations you feel stuck in a vicious circle or loop, or you start digging or pull out your shovel. Notice in what ways your spirit pushes you to dig (what thoughts, emotions, or sensations it gives you). Notice what happens when you try to dig in order to get out. Write down what you notice in the table below:

Day	Situation	What thoughts did you notice?	What emotions were present?	What physical sensations did you notice?	What behaviours were present?	How did you face it/handle it?
Monday						
Tuesday						
Wednesday						
Thursday						

WEEK 2 — WHY ISN'T IT WORKING?
DISTANCING BEHAVIOURS

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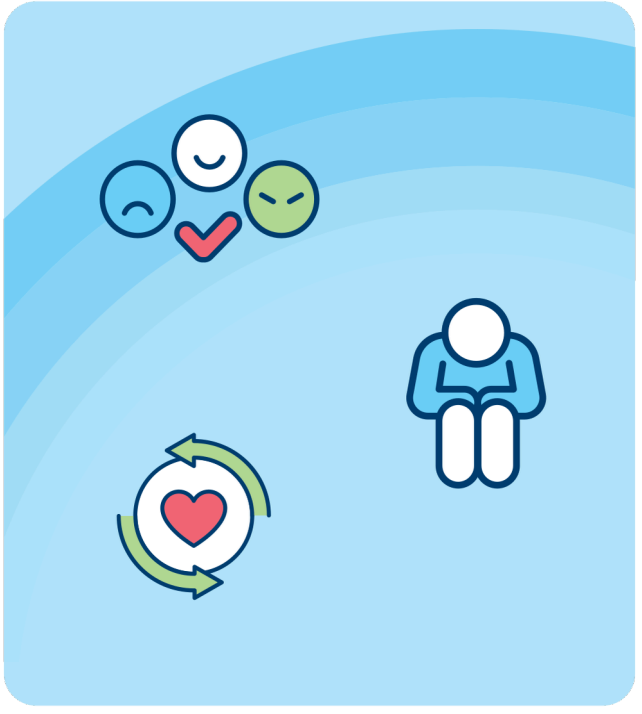
Friday						
Saturday						
Sunday						



WEEK 3

**Make room for
or fight against**

WEEK 3 — MAKE ROOM FOR OR FIGHT AGAINST

Learning to make space for my emotions

During this session, Alex talks about a wave of shame that submerged him this week. “I thought of all of the moments where I failed. It suffocated me.” The therapist explains that emotions, even the most painful ones, are not enemies. He proposes a mindfulness exercise: “Imagine that your emotions were waves. You will see small ones, medium ones, and large ones. Rather than running from them, try to observe them. They will last a moment, and then they will end up passing.”

During the week, Alex tries the technique. One evening, when he feels a strong urge to drink, he sits in his living room and closes his eyes. He observes the urge like a wave that at the beginning is powerful, but eventually loses its intensity. When he reopens his eyes, he feels a bit stronger. “I did not give in this time.”

The therapist then asks him to reflect on other emotions that they could try to let pass without acting on. Alex mentions the anger that he sometimes feels towards himself when he thinks back on his past mistakes. Together, they discuss strategies for observing the anger and understanding it instead of trying to fight it or drowning in it.

He notes in his journal: “I’m realizing that I can just feel my emotions, even if they are not pleasant.” He thinks back to the exercise of the pink elephant that he did during his appointment…

And you, can you observe within yourself this week, without judgment, to better understand your reactions?

WEEK 3 — MAKE ROOM FOR OR FIGHT AGAINST

Objective

Learning to move forward with what is happening inside of me.

Concepts

- Discovering how my thoughts and emotions function.
- My thoughts and emotions are not facts, but rather phenomena that occur spontaneously.
- Fighting against my thoughts and emotions can strengthen their hold.
- Developing strategies to welcome my thoughts and emotions and make room for them.

Exercice

Observe an uncomfortable thought or emotion
and practice the steps of acceptance.

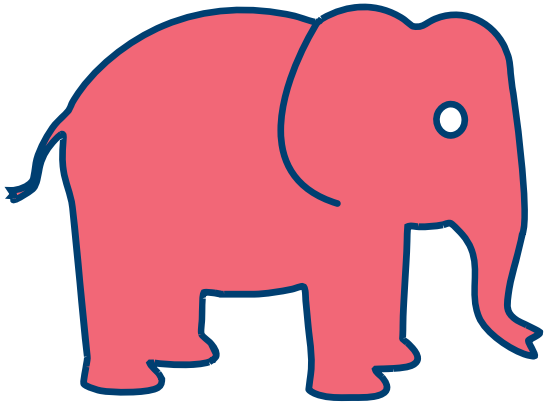
WEEK 3 — MAKE ROOM FOR OR FIGHT AGAINST

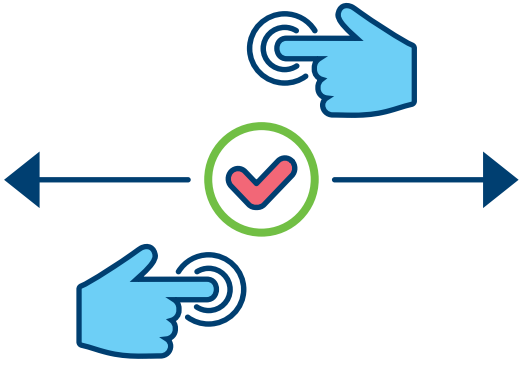
Notice: Notice what I am feeling and name it (I feel sad, I am disappointed, etc.).

Allow: Tolerate the presence of the emotion; feel it in the moment and observe how it manifests itself.

Welcome: Take deep breaths, soothe yourself with comforting words and gestures.

Adapt: Take the time to decide how I want to move forward with this experience.





WEEK 3 — MAKE ROOM FOR OR FIGHT AGAINST

Openness or fight

Steps	What is it?	How do I do it?
1. Resist	Fighting against what presents itself. It is often the first reflex that occurs.	
2. Recognize	Turning oneself towards the discomfort, towards what is felt inside, with curiosity.	
3. Allow	Tolerate safely. Hang in there. I don't like it, but I can experience it, bear it for the moment.	
4. Welcome	Allow feelings to come and go. It's okay, I am able to make space for it.	
5. Adapt	See the value of difficult emotional experiences. What can I learn from it? How can I move forward with what is presenting itself?	

WEEK 3 — MAKE ROOM FOR OR FIGHT AGAINST

Openness or fight

Day	Painful feelings came up. What triggered them?	How much did I fight against? 0= No fighting 10= Maximum fighting What fighting behaviours appeared?	Were you able to: recognize, allow, welcome or adapt? Check the ones you were able to do: What did you notice?
Monday			○ Recognize ○ Allow ○ Welcome ○ Adapt
Tuesday			○ Recognize ○ Allow ○ Welcome ○ Adapt
Wednesday			○ Recognize ○ Allow ○ Welcome ○ Adapt
Thursday			○ Recognize ○ Allow ○ Welcome ○ Adapt

WEEK 3 — MAKE ROOM FOR OR FIGHT AGAINST

Openness or fight

Day	Painful feelings came up. What triggered them?	How much did I fight against? 0= No fighting 10= Maximum fighting What fighting behaviours appeared?	Were you able to: recognize, allow, welcome or adapt? Check the ones you were able to do: What did you notice?
Friday			○ Recognize ○ Allow ○ Welcome ○ Adapt
Saturday			○ Recognize ○ Allow ○ Welcome ○ Adapt
Sunday			○ Recognize ○ Allow ○ Welcome ○ Adapt

An evolving, patient-adapted acceptance and commitment therapy

WEEK 4

Urge surfing

WEEK 4 — URGE SURFING

Mindfully surfing your urges

Alex arrives to this session with an anecdote, but also appears hesitant. He starts softly, as if he isn't sure about the value of what he is about to say. "The other day, I had a very strong urge to drink. I had already opened the fridge and my hand was on a beer." He pauses and stares at a point on the ground. "Usually, I don't think about it, I take it, but this time, I stopped myself. I heard your voice in my head, and so I decided to try to watch it pass."

He raises his eyes towards the therapist, his features marked by a slight uncertainty. "It was so hard. I was afraid that it wouldn't work, that I would be too weak, but you know: I succeeded." Alex smiles timidly, as if he doesn't yet dare believe in this victory. The therapist smiles reassuringly, reinforcing his budding feelings of pride.

The therapist congratulates him and introduces a new tool: the SOBER breathing space. When Alex feels an urge, he can pause, breathe deeply, observe what is happening in his body, and choose a different response. They practice together: Alex closes his eyes, inhaling deeply and imagines his craving like a wave that rises and falls. He starts to feel a sense of control.

The therapist also asks Alex to note what he feels after having resisted the urge. Alex answers: "It surprised me, but I felt proud." This realization encourages him to continue.

This week, Alex decides to try the technique every time he feels an urge. He notes in his journal: "Maybe I can surf my urges, instead of letting them submerge me."

They discuss other moments where this technique could be useful, like during arguments with loved ones. Alex tells himself that he will try to pause before responding when he feels overwhelmed by frustration.

And you, what could you do differently this week to surf your urges?

WEEK 4 — URGE SURFING

Objective

Learn to surf urges.

Concepts

- My urges are temporary and diminish with time.
- Developing my ability to recognize my urges with tools like breathing and coping differently with these urges.
- I am the captain of the ship : I can choose my actions, even in the face of very strong urges.

Exercise

Practice surfing my urges in order to observe them without following or succumbing to them.

WEEK 4 — URGE SURFING

WEEK 4 — URGE SURFING

This week's exercise

SOBER — Breathing space

This technique can be used at any time, to take a break, get out of *"autopilot"* and choose an action guided by your values (instead of reacting to your thoughts, emotions, or impulses).

S — Stop

The first thing to do when you find yourself in a stressful or at-risk situation is to slow down. Stop. Give yourself a moment to get out of autopilot and start to notice what is going on for you.

O — Observe

Notice what is manifesting in terms of sensations and thoughts. Describe each of these by telling yourself "I think that…", "I have the sensation that…" Notice everything that you can about your experience.

B — Breathe

You can use the breathing exercise at every meeting during the short mindfulness session. Afterwards, pay attention to your breathing for a few moments.

E — Expand

Notice what you are experiencing and how you have lived those experiences. Take a step back and observe yourself from a larger view of your current situation. Take away something you have learned that will be useful for another time.

R — Respond

Respond mindfully, by identifying what is best for you in this situation. For this, let yourself be guided by what is the most important to you, even in the presence of obstacles that your mind might be sending you in this moment.

WEEK 4 — URGE SURFING

Practice (continued)

We encourage you to practice SOBER space breathing. When you are in line at the store, when you are walking somewhere, when you feel stuck in a stressful situation or any other situation, practice SOBER space breathing. The more you train yourself to get out of autopilot, the more you will be able to do it in situations where it really counts. Note what you notice in the table below:

Stop
Observe
Breathe
Expand
Respond

Day	Situation	How did your practice go? What did you notice during and after about one or some elements of the SOBER breathing space? What parts were the easiest or the most difficult to intergrate?
Monday		
Tuesday		
Wednesday		
Thursday		

WEEK 4 — URGE SURFING

Practice (continued)

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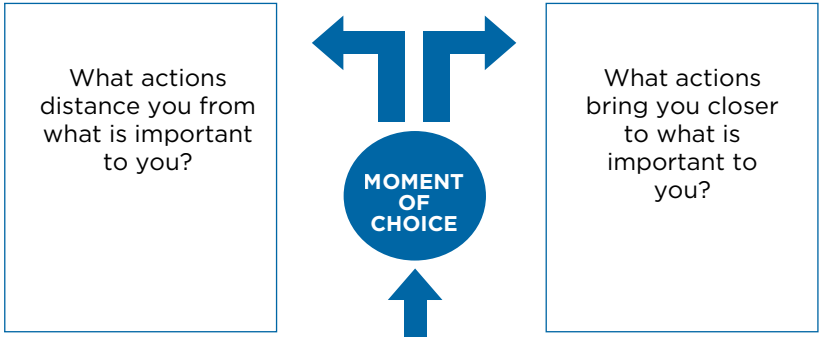
Respond

Day	Situation	How did your practice go? What did you notice during and after about one or some elements of the SOBER breathing space? What parts were the easiest or the most difficult to intergrate?
Friday		
Saturday		
Sunday		

WEEK 4 — URGE SURFING

Craving: moment of choice



TRIGGERS

What thoughts, emotions, sensations or memories increase the probability of using?

What does your brain tell you to push you to act/use

HELPERS

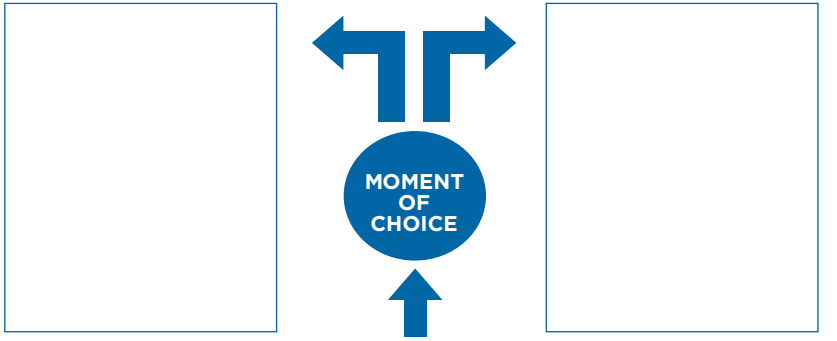
What habits and strategies can help you let go of these urges?

What does your experience tell you will happen to your urge if you do not respond to it?

URGES

Physical sensations	Thoughts	Emotions	Memories

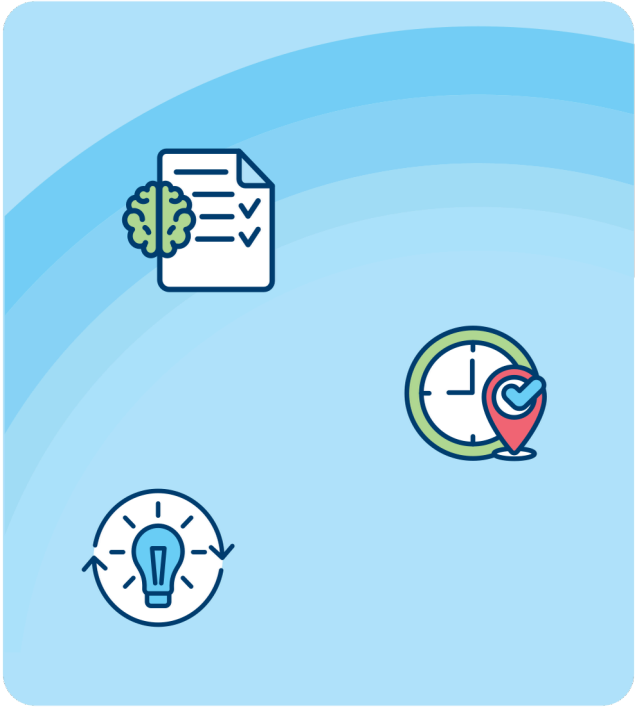
High risk situation: What inner/outer triggers brought about this urge?



TRIGGERS

HELPERS

URGES



WEEK 5

Reactivating my life

WEEK 5 — Reactivating my life

Committing to action

Alex arrives to this session with a newfound energy, but also a profound reflection. “I’ve realized that I spent so much time avoiding things, that I don’t do anything anymore that matters to me.” He pauses, his eyes fixed to the floor, and he adds “Last night, I sat with my guitar and I just strummed a few chords. It was nothing big, but it was…calming. It reminded me that I used to really like that. It also made me think that there are so many things that I used to like that I don’t do anymore…”

He raises his eyes, hesitant: “But it’s as if, each time that I try to do something, a little voice in my head tells me that it serves no purpose, that I will fail again.”

The therapist encourages him gently: “And, despite that voice, you picked up your guitar yesterday. It’s a great victory, Alex.” Alex gives a hint of a smile, taking a moment to let the compliment sink in and murmured: “Maybe I can try again.” The therapist encourages him to identify a simple action that he might take to activate himself. Alex mentions his guitar, but he also adds that he would like to reconnect with his family.

They create a plan together and Alex commits to calling his sister this weekend to propose a dinner. He is nervous but he tells himself “I want to try, even if it isn’t perfect.” They also talk about another objective to play a piece of music on his guitar the next week. “That will be my challenge.”

The therapist asks him how he feels about the idea of doing these actions. Alex admits that he is scared that he won’t succeed, but also he feels a bit of excitement. “It’s been a long time since I’ve felt like doing something.”

By discussing, Alex and the therapist identify possible obstacles and plan how to overcome them. For example, if his sister is busy, Alex plans to propose a new date instead of giving up.

When he leaves the session, Alex feels a mix of apprehension and excitement. “Maybe I can start to build something new.”

And you, what action could you take this week to reactivate yourself?

WEEK 5 — REACTIVATING MY LIFE

Objective

Taking action to reactivate myself.

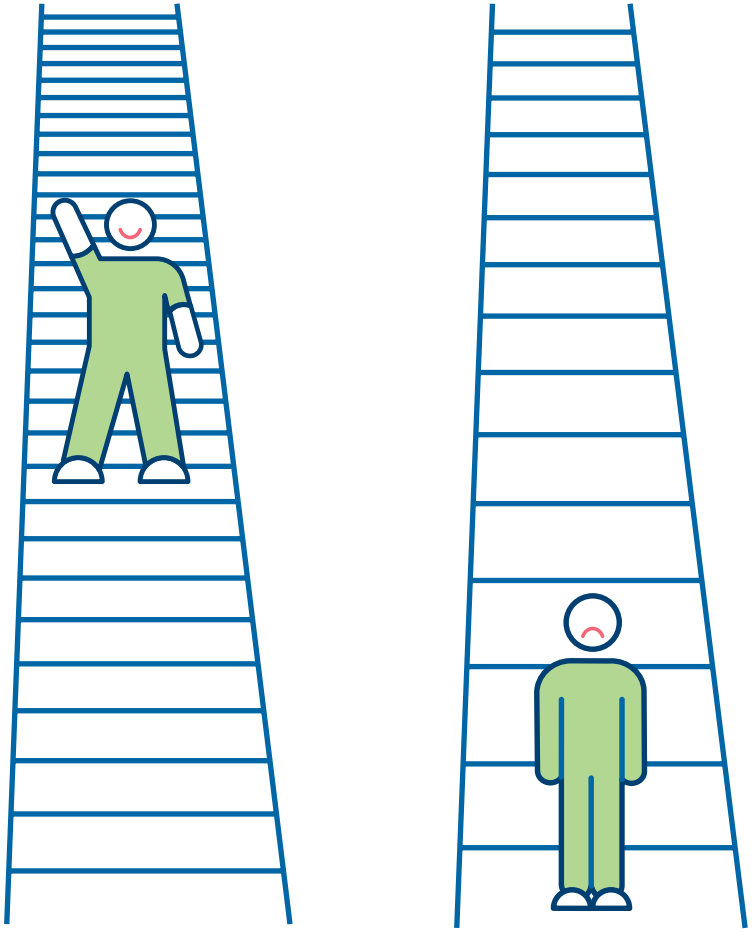
Concepts

- Identifying the actions I want to take.
- Identifying my obstacles.
- Going step by step.
- There are no small steps.

Exercise

Choosing and taking an action.

WEEK 5 — REACTIVATING MY LIFE



WEEK 5 — REACTIVATING MY LIFE

Exercise

Choose a behaviour/action that you want to do this week. Example: go take a walk, drink less liquor, eat fewer chips, etc., and accomplish it by applying the 7 forces of change, all while breaking it into steps that are smaller and more attainable.

Ladders

This concept puts the emphasis on breaking down objectives into small, attainable goals. Each step reinforces confidence and drive, helping to maintain the progress that you make through time.

Community

The support of a group or a network is crucial for maintaining motivation. Being part of a community can provide responsibilities, encouragement and shared experiences that reinforce your commitment towards change.

Important

Understanding why change is important for you personally can reinforce determination. Linking the change to what is important and your long term goals makes it more significant.

Easy

Making changes as simple as possible can increase the probability of success. Reducing barriers and creating an environment that facilitates desired behaviours helps establish new habits.

Mental strategies

These are strategies based on neuroscience that make use of the way our brains work to favour change. Techniques such as visual reminders or positive reinforcement can improve motivation and the retention of new behaviours.

Captivating and pleasant

Being interested and involving your interest and emotions makes the process of change more pleasant. Finding the means to render the experience exciting or gratifying can help maintain motivation.

Taking root

This refers to the process of integrating new habits into your routine up until they become automatic. Consistency and repetition are essential to render the behaviours automatic through time.

WEEK 5 — REACTIVATING MY LIFE

Day	Behaviour/action	What did you notice after you did or did not do the action? (FEAR OU DARE)
Monday		
Tuesday		
Wednesday		
Thursday		

Fusion with your thoughts
Evaluation of experience
Avoidance of experience
Reason-giving for behaviour

Defusion
Acceptance of discomfort
Realistic goals
Engage in what is important

WEEK 5 — REACTIVATING MY LIFE

Day	Behaviour/action	What did you notice after you did or did not do the action? (FEAR OU DARE)
Friday		
Saturday		
Sunday		

Fusion with your thoughts
Evaluation of experience
Avoidance of experience
Reason-giving for behaviour

Defusion
Acceptance of discomfort
Realistic goals
Engage in what is important

WEEK 6

Committing to what is truly important to me

WEEK 6 — COMMITTING TO WHAT IS TRULY IMPORTANT TO ME

Exploring your values

Alex arrives this week and shares that he surprised himself by thinking more about what he considers important in his life. When he thinks about his family, he feels a mix of love and guilt, a weight that he has difficulty naming. “I want to do better, but I don’t always know how to start.” His hands tighten a bit on the armrest, as if he is fighting against a fear of not being good enough. He admits “And if I fixed goals for myself, but I don’t reach them? I don’t want to disappoint my sister yet another time.”

The therapist listens to him attentively, offering him the space to express his worries. Alex adds after a moment of silence: “But I also want to try. It scares me, but it motivates me also...a bit.”

The therapist invites him to **deepen this question** further by exploring different categories of values: relationships, health, work, hobbies. Together, they talk about what values these signify, in concrete terms, for Alex. For example, in regards to health, Alex mentions that he wants be full of energy and sleep better, while, for relationships, he expresses a desire to spend more time with his loved ones and to be more present.

The therapist proposes an exercise: imagine an ideal day during which Alex would live fully according to his values. Alex describes a day where he would wake up early, go for a stroll, play the guitar and pass the evening with his sister and his nieces. When describing this day, he feels a light excitement “It looks nice. Not perfect, but nice.”

And you, what are the values that guide you and how could you put them in action this week?

WEEK 6 — COMMITTING TO WHAT IS TRULY IMPORTANT TO ME

Objective

Clarify what is important to guide my actions.

Concepts

- My values are like a compass: they guide my choices.
- Living according to what is important to me helps me give my life meaning.
- Identifying my obstacles in pursuit of a life that I want.
- Accepting that obstacles are inevitable and are the driver of change.

Exercise

Reflecting on what is important and act accordingly.

WEEK 6 — COMMITTING TO WHAT IS TRULY IMPORTANT TO ME

WEEK 6 — COMMITTING TO WHAT IS TRULY IMPORTANT TO ME

Exercise : clarifying your values

Deep inside of yourself, what is important to you? What do you want your life to represent? What kinds of qualities do you want to cultivate as a person? How do you want to be in your relationships with others? Values are the deepest desires of our hearts in regards to the way we want to act and engage with other people and ourselves. They are the guiding principles that motivate us throughout our entire lives. Values are different than goals. Values imply a continuous action; they are like directions that follow us, while goals are what we want to obtain along the way.

The Bull's-eye: The target on the following page is divided into four important life domains: work/education, hobbies, personal development/health and relationships (intimate/family/social). To start, note your values in these 4 life domains. Not everyone has the same values and it is not a test to see if you are "good." Think in terms of general direction in life, rather than in terms of specific objectives. Note what you would do if there was nothing blocking your way, nothing that was stopping you. What is important?

What matters to you? Is this what you would like to reach for? Your values should not be a specific objective, but rather, think about the way that you would like to live your life over time. For example, accompanying your son to a football match could be an objective; being an implicated and interested parent could the the underlying value. Notice: make sure that they are really your values, and not the values of someone else. It's your personal values that are important.

(Adapted from a worksheet by Tobias Lundgren)

WEEK 6 — COMMITTING TO WHAT IS TRULY IMPORTANT TO ME

Exercise : clarifying your values

1. **Work/education:** refers to your place of work and your career, to your education and knowledge, to the development of competencies. This can include volunteering and other forms of unpaid work. How do you want to behave towards your clients, colleagues, employees and other workers? What are the personal qualities that you want to bring to work? What are the competencies that you want to develop?

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2. **Intimate/family/social relationships:** this refers to intimacy, proximity, friendships and social bonds in our lives. This includes a relationships with a partner, your children, your parents, your loved-ones, your friends, your work colleagues and other social contacts. What type of relationships do you want to build? How do you want to behave in those relationships? What are the personal qualities that you want to develop?

.....

.....

3. **Personal development/health:** refers to your continuous development as a human being. This can include religion, personal expressions of spirituality, creativity, the development of life skills, meditation, yoga, going out in nature, exercise, nutrition or the fight against risk factors to your health, like cigarette smoking.

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4. **Hobbies:** refers to the way that you play, that you relax, that you stimulate yourself or that you have fun; your pastimes or other resting activities, hobbies, having fun and creativity.

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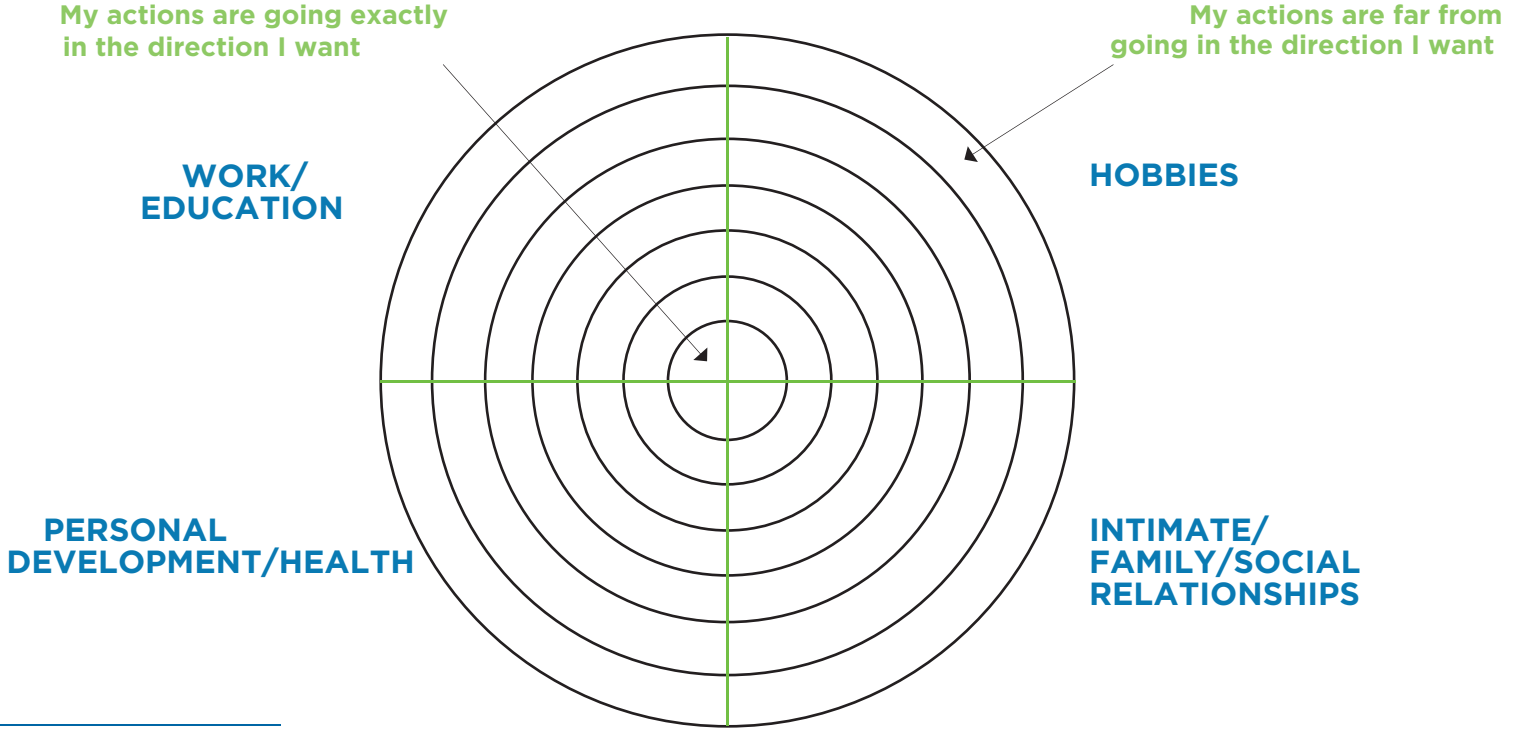
(Adapted from a worksheet by Tobias Lundgren)

WEEK 6 — COMMITTING TO WHAT IS TRULY IMPORTANT TO ME

Targeting actions towards values

On the target below, note with an **X** to what extent your actions in the last week went in the direction of what was important for you, in each of the large life domains. An **X** in the center of the target signifies living fully within your values in this life domain. Given that there are four valued life domains, you need to write four **X**s on the target.



WEEK 6 — ENGAGING IN WHAT IS TRULY IMPORTANT TO ME

Doing what is important

This week, we encourage you to work on values that are important to you. Name 2 or 3 values that you want to put into practice throughout the day. Try to integrate these values into your day. Pay attention to actions that bring you closer to what is important to you and to missed occasions to engage in valued actions.

Write down what you have noticed in the table below:

My values:

Day	Situation	Did you engage in an action according to what is important or did you notice obstacles?	If you engaged in what was important, briefly describe it and what you felt
Monday			
Tuesday			
Wednesday			
Thursday			

WEEK 6 — ENGAGING IN WHAT IS TRULY IMPORTANT TO ME

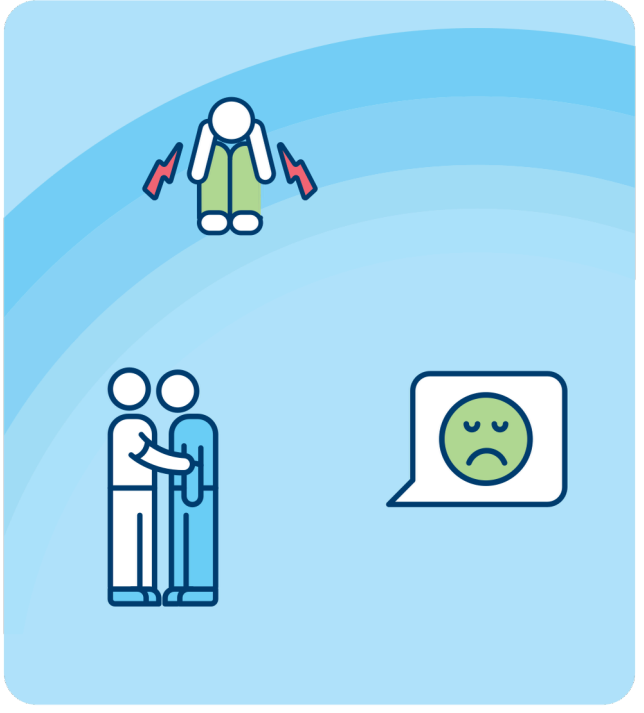
Doing what is important (continued)

This week, we encourage you to work on values that are important to you. Name 2 or 3 values that you want to put into practice throughout the day. Try to integrate these values into your day. Pay attention to actions that bring you closer to what is important to you and to missed occasions to engage in valued actions.

Write down what you have noticed in the table below:

My values:

Day	Situation	Did you engage in an action according to what is important or did you notice obstacles?	If you engaged in what was important, briefly describe it and what you felt
Friday			
Saturday			
Sunday			



WEEK 7

Shame

WEEK 7 — SHAME

Make room for shame and move forward

This week, Alex arrives a bit disturbed, shoulders slightly hunched. He hesitates a bit before speaking, casting furtive glances around him as if he was searching for words or fearing judgment. Finally, he breathes in deeply and starts: “There was an incident this week…” He pauses, then continues in a low voice, almost as if confessing it to himself. “I got into a fight with my sister. I said something that I regret, and now I don’t know how to make up for it.” His hands tremble lightly, making visible the anxiety that he has about sharing this episode.

The therapist encourages him to see this incident as a learning opportunity. Together, they discuss shame (which is different from guilt) as a universal emotion, profoundly human, related to the desire that humans have to feel loved and connected to others, but also a temporary emotion that can guide towards behaviour more aligned with our values. “What do you wish you had said or done differently?” asks the therapist.

Alex reflects and says that he wishes he would have listened more instead of responding defensively. They explore together how he could express his regrets and repair the relationship. Alex decides to write a letter to his sister to explain to her what he felt and to apologize sincerely.

In talking about this plan, Alex feels a mix of nervousness and relief. He realizes that he can advance despite his mistakes. The therapist reminds him that every effort counts and what is important is to continue learning.

And you, how can you transform a moment of guilt into an opportunity to grow this week?

WEEK 7 — SHAME

Objective

Reduce the negative impact of shame on my life.

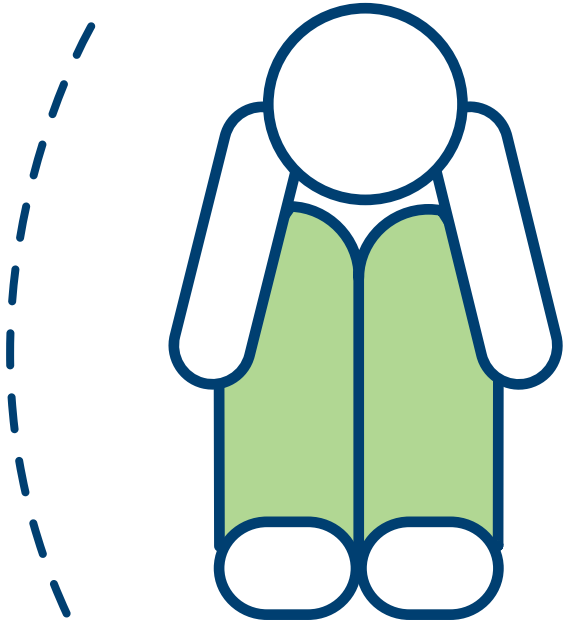
Concepts

- Shame affects my identity and can distance me from myself and others.
- Identifying my thoughts and behaviours related to shame.
- Recognizing shame as a universal emotion and learning to move forward in its presence.

Exercise

Observe a situation where you felt shame.

WEEK 7 — SHAME



WEEK 7 — SHAME

Step 1 — Exploring shame

Moving from shame to guilt	
What are the events or the situations that trigger shame?	
Notice your thoughts when you feel shame. What physical sensations do you experience when you feel shame? What is your body language or posture when you feel shame?	
Describe situations where you avoid your shame:	
Think of a moment where you listened to your shame. What did you experience?	

***Shame** is an emotion related to a judgment about our person and it is usually unconstructive;
Guilt it an emotion related to behaviours we have engaged in, and it may lead us to take reparative actions.

WEEK 7 — SHAME

Step 2 — Exploring shame

Next steps	What did you do or try?
When we feel shame, it is generally not the time to act quickly. In general, we need to first take care of ourselves before acting. Here are several options for how to take care of yourself once you have noticed shame. We encourage you to experiment with the options that are the most useful/appealing to you. Check off the ones that you decide to try: ☐ Give a label to the sensation felt. For example: "It's my heart that is beating fast." or "It's numbness." Practice labelling until you find the labels that correspond to your experience. ☐ Validate the sensation. Use a script for yourself: "It's logical that I am experiencing this because _____." ☐ Validate the pain that you feel by telling yourself "ouch" or "it hurts," as you would do it for a child that just fell: "This knee hurts, does't it?" ☐ Place a hand on the place on your body that hurts the most. See if this part of your body can feel the heat of your hand. Tell yourself compassionate phrases like "Let the part of me that is hurting be safe, let the part of me that is hurting be well, let the part of me that is hurting be comfortable. ☐ Breathe deeply. A slightly longer inhale and exhale of your breath engages the parasympathetic nervous system ("rest and digest") and can have a soothing effect.	

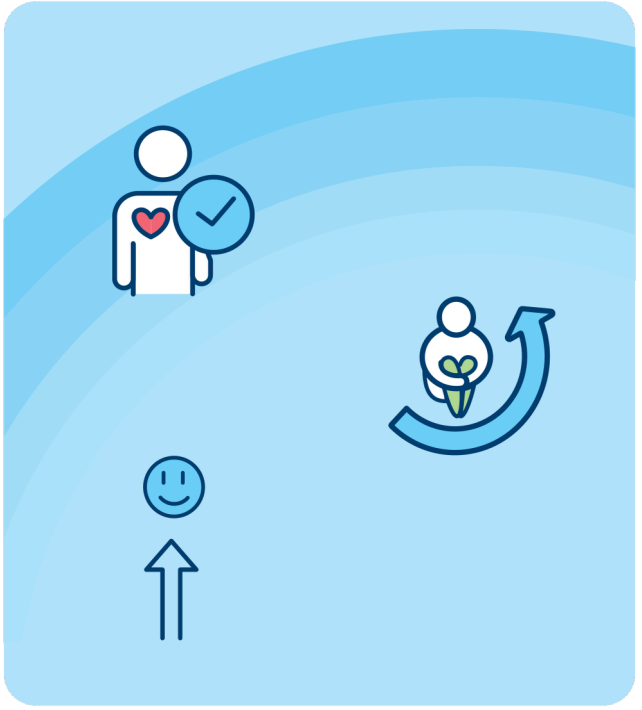
*__Shame__ is an emotion related to a judgment about our person and it is usually destructive;
__Guilt__ it an emotion related to behaviours we have engaged in, and it may lead us to take reparative actions.

WEEK 7 — SHAME

Step 2 — Exploring shame (continued)

Next steps	What did you do or try?
☐ Remind yourself of the people who support you, even if it is only one person. Write "_____ supports."	
☐ Offer yourself something physically warm, like a cup of hot tea or a warm bath. Research shows that physical warmth contributes to feelings of emotional warmth.	
☐ Practice a mantra, meaning, a phrase that is sacred/repetitive, that reminds you that shame is human. You can envision phrases such as: "Shame is human", "Other people feel shame, too", or "I am not alone."	
☐ If you feel a crushing shame, it can be disorienting. In that case, it can be useful to notice the sensation of your body sitting in a chair or of your feet touching the floor, or using an even stronger physical experience to connect to the present moment. For example, you can try holding an ice cube or eating a very sour candy. In addition, it can be useful to activate your sympathetic nervous system by doing vigorous exercise, like running in place of jumping rope for around 60 seconds.	
Did you try other techniques?	
What was the most soothing for you?	
Adapted from: //www.actwithcompassion.com/august_2016_tool_of_the_month	

***Shame** is an emotion related to a judgment about our person and it is usually destructive;
Guilt it an emotion related to behaviours we have engaged in, and it may lead us to take reparative actions.



WEEK 8

Compassion

WEEK 8 — COMPASSION

Projecting yourself into the future

For this last session, Alex arrives with a feeling of accomplishment, but also a bit of apprehension. “It’s weird to think that this is the end. I wonder if I will be able to continue on my own.”

The therapist starts by recognizing the road that Alex has travelled “Look at what you did these last few weeks. You explored what was important for you, found new ways to cope with your emotions and even started rebuilding bonds with your family…All of that, you’re the one who did it.” Alex smiles, a bit embarrassed, but visibly touched by these words.

The therapist continues gently, “You know, Alex, I notice that you often have a tendency to be hard on yourself. But, imagine that you are talking to a close friend in the same way that you sometimes speak to yourself. What would you tell them if they were going through what you have been through?” Alex reflects a moment, and answers: “I would tell them that they are doing their best, and already that is huge, and they should be proud of themselves.”

The therapist agrees. “Exactly, and if you tried to speak to yourself with the same compassion, to treat yourself the way you would treat your best friend or a good sports coach: “Encourage instead of criticize.”

Alex remains pensive. “I never thought of it that way…”

Maybe I could try. It costs nothing to try.”

After they go through the tools again that Alex learned throughout the program. The therapist proposes that they create a “plan for the future” to continue using the most useful tools regularly. Together, they identify the domains where Alex would like to continue progressing, like taking care of his physical health and deepening his family relationships.

Alex decides to fix a few concrete goals for the upcoming weeks. He commits to returning to some light physical activity, like yoga, and to planning a family outing each month. “They are small steps, but I want to do them” even if it isn’t easy. The therapist highlights the importance of celebrating each effort, no matter how modest, and reminds Alex that he can always come back to consult if he needs.

Before leaving, Alex shares a reflection “I still have doubts sometimes, but I feel better equipped. And most of all, I don’t feel as alone in all of this.” He leaves the session with a mix of gratitude and apprehension, ready to continue his journey.

And you, what tools or actions did you learn recently that you can integrate into your life in order to move towards your goals?

WEEK 8 — COMPASSION

Objective

Supporting myself.

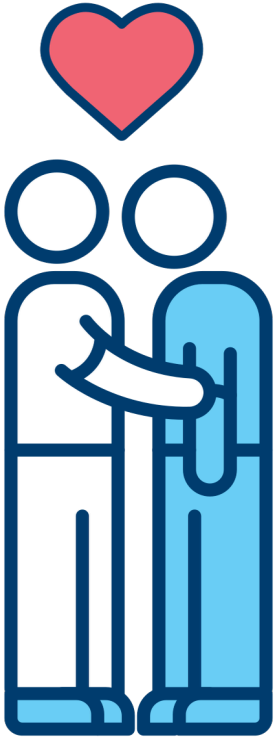
Concepts

- Self-compassion consists of treating myself with gentleness and kindness.
- Three pillars: mindfulness, shared humanity (you are not alone) and kindness towards yourself.
- Supporting myself in difficult moments, like a kind coach or a friend.

Exercise

Practice a self-compassion break to respond to difficult moments with gentleness and understanding.

WEEK 8 — COMPASSION



WEEK 8 — COMPASSION

Working FOR or AGAINST yourself
Cultivating compassion and kindness

Day	Fill in the thoughts and the self-criticism that can present itself*	1 Being present with yourself and mindfulness Notice how you are present for yourself in kindness	2 Common and shared humanity Relate yourself to the human condition and the connection of that to suffering (as it is for you and all humans)	3 Kindness towards yourself Fill in the thoughts or gentle acts of comfort, of support for yourself
Monday				
Tuesday				
Wednesday				
Thursday				

*Judgment, critique, blame, devalorization, shame, self-disgust.

WEEK 8 — COMPASSION

Working FOR or AGAINST yourself
Cultivating compassion and kindness

Day	Fill in the thoughts and the self-criticism that can present itself*	1 Being present with yourself and mindfulness Notice how you are present for yourself in kindness	2 Common and shared humanity Relate yourself to the human condition and the connection of that to suffering (as it is for you and all humans)	3 Kindness towards yourself Fill in the thoughts or gentle acts of comfort, of support for yourself
Friday				
Saturday				
Sunday				

*Judgment, critique, blame, devalorization, shame, self-disgust.

An evolving, patient-adapted acceptance and commitment therapy

WEEK 9

Qualitative Interview

WEEK 9 — MEMORY AID FOR THE QUALITATIVE INTERVIEW

ACKNOWLEDGMENTS

We wish to express our profound gratitude to the people who contributed to the development of this therapy and the development of this therapy booklet.

Our thanks are primarily addressed to Dr. Élie Rizkallah and Dr. Marie-Josée Prévost, for their expertise and their humanity; to Mrs. Céline Carrier, graphic designer, for her artistic eye and patience; to Dr. Patricia Garel and Dr. Laurent Garel, for their attentive readings and precious comments; to Dr. Didier Jutras-Aswad and Dr. Simon Dubreucq for their support and advice; as well as to Dr. Nicolas Garel and Dr. Kyle T. Greenway, without whom this therapeutic approach and the Montreal Model would not have seen the light of day. We equally thank the patient partners. Finally, we warmly thank the CHUM, whose institutional support allowed for the development of this project.


CRCHUM
CENTRE DE RECHERCHE
Centre hospitalier
de l'Université de Montréal


CHUM
Centre hospitalier
de l'Université de Montréal

Date: _____ Name of interviewer: _____

Duration: _____ Participant code: _____

Semi-structures interview

Obtain consent to record and then start the recording

1- Introduction

As a reminder, the objective of this secondary study is to understand the subjective experience of ketamine-assisted psychedelic psychotherapy among individuals diagnosed with a depressive disorder comorbid with alcohol use disorder.

The purpose of this interview is to better understand your experience with ketamine-assisted psychotherapy in relation to your symptoms of depression and your alcohol use. In the main study, ketamine-assisted psychotherapy is administered as a treatment that uses ketamine in a controlled therapeutic setting to help patients explore and modify their thoughts, emotions, and perceptions. In this secondary study, your experience with ketamine-assisted psychotherapy is being explored. It refers to your personal journey and impressions throughout the different stages of the treatment.

This interview will be recorded so that your responses can be transcribed and analyzed afterward. The recording of the interview, as well as any personal information, will be deleted immediately after transcription. The data obtained from the interview will remain confidential, and only the researchers involved in the study will have access to it until it is destroyed at the end of the study.

You are invited to respond freely to the questions that will be asked. Please note that there are no right or wrong answers. At any time, you may take a break or stop the recording. I also encourage you to let me know if you experience any discomfort during the interview. This interview will last approximately one hour.

2- Interview questions

- ➢ Experience of depression and alcohol use before KAP
  - Can you describe your experience with depression and alcohol use before the therapy? *What symptoms did you experience? What was it like for you?*
  - Can you explain to me the context in which you experienced your first depressive episode? *For how long have you been diagnosed with this disorder?*

- ➢ Experience with ketamine-assisted therapy
  - How did you come to participate in this study?
  - What were your expectations before starting treatment?
  - How are you doing since starting treatment?
  - What were the most notable parts of your experience during the ketamine infusion sessions?
  - What were the most memorable parts of your experience during the psychotherapy sessions?
  - *What was your relationship with the care team like during the treatment?*

- ➢ Evolution of perception throughout treatment
  - Have you noticed changes in your way of perceiving ketamine-assisted therapy before, during and after treatment?
  - Have you notice changes in your way of thinking, feeling, or perceiving things before, during, or after treatment?
  - Were you able to complete your ketamine-assisted psychotherapy treatment?

- ➢ Integration of treatment effectiveness according to your experience
  - How do you perceive the effects of treatment on your depressive symptoms and alcohol use?
  - To what degree do you think ketamine-assisted psychotherapy was beneficial for you?
  - If you had to explain ketamine-assisted psychotherapy to someone who was about to undergo it, how would you describe what you experienced to that person?

- ➢ General perceptions and impressions
  - In your opinion, what were the expectations of the research team regarding the main study? What were their expectations of you?
  - Do you have suggestions for improving this type of treatment in the future?
  - Is there something else you would like to share about your experience with ketamine-assisted psychotherapy? Are there things you would like to address about any of this?

3 - Conclusion

- Questions to add

We've gone through all of the interview questions. Is there anything you would like to add on this topic?

- Feedback on your experience

How did the interview go for you today?

- Confidentiality of data and information regarding the follow-up of the study

I would like to remind you that the data will be used to gain a better understanding of participants' experiences with ketamine-assisted psychotherapy. This will, among other things, allow for the production of a scientific article on the topic. The data will remain confidential at all times and will be destroyed at the end of the study.

- Summary of the study results

Would you like to receive a summary of the study results once the study is finished?

Yes ☐ No ☐

- Possibility of addressing additional questions

Of course, I remain available should you have any questions regarding the project, and I would be happy to answer them.

Thanks for participation and provision of contact information