## 5.0 METHODOLOGY

### 5.1 DESIGN OF THE STUDY

This study is classified into three stages.

Phase 1- Development of a Yoga Based Counselling module

Phase 2 –Validation of the Yoga Based Counselling module

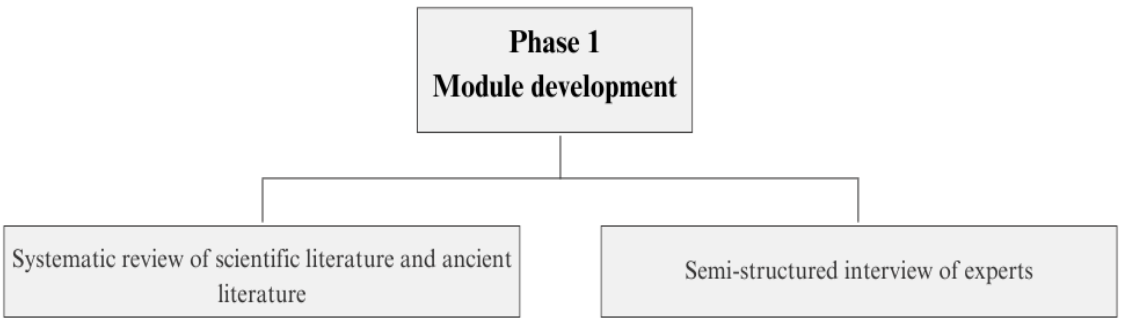
Phase 3- Feasibility testing of the validated Integrated Yoga module as adjunct therapy for patients with SUD

The inductive method of qualitative inquiry was followed to develop the YBCP along with the quantitative method of Content Validity Ratio (CVR) for validation. The design adopted for this study is a quasi-experimental pilot study.

### 5.2 PROCEDURE

#### 5.2.1 Phase 1: Development of the Integrated Yoga module as add-on treatment for SUD (Figure 3)

**Figure 3: Illustration of Phase 1 – Module Development**



#### 5.2.1.1 Systematic Review

Traditional yoga literature (Iyengar, 2002)(Heimann, 1935)(Vivekananda, 2021)(Śaṅkarācārya. & Swarupananda, 2007) contemporary yoga texts(Nagendra et all, 1991; Saraswati, 2008) and research studies were reviewed in order to gather the yogic practices which can directly or indirectly manage SUD and its related symptoms. Traditional yoga texts such as *Bhagavad Gita, Patanjali Yoga Sutra, Yoga Vashistha, Ramayana, and Upanishads* were reviewed for collecting relevant information. Published articles from inception till August 2021 were identified through Web of Science, Scopus, and MEDLINE/PubMed databases using the Boolean operators ((“counseling” OR “psychotherapy” OR “counsel”) OR “counseled” OR “counselings” OR “counselled” OR “counselling” OR “counseling” OR “counseling” OR “counsellings” OR “counsels”) AND (“yoga” OR “yogic” OR “bhagavad gita” OR “Patanjali” OR “ramayana”)). Studies which focused only on the asana, pranayama and meditative aspects of yoga instead of psychotherapy were excluded from the search. There were no limitations pertaining to the study type. However, literature which did not provide sufficient information about yogic counselling were excluded. The selected articles were coded and qualitatively analysed using an inductive thematic approach. A preliminary open coding was conducted and themes and sub-themes were grouped. These formed the basis for the interview.

#### 5.2.1.2 Interview of Experts

In order to have an in-depth understanding of YBC, interviews of experts were carried out. An online qualitative interview was conducted using a semi-structured interview guide with open-ended questions based on the themes and sub-themes from the literature review. Yoga experts with a minimum of 10 years of experience in yoga therapy or a Ph.D. in Yoga were selected.

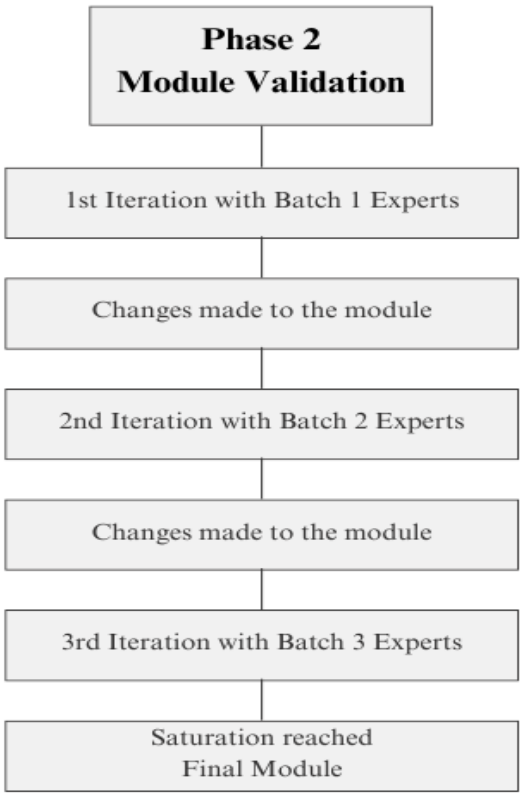
The interviews were audio recorded, transcribed, coded, and qualitatively analysed. Themes and sub-themes were categorised and repeated themes were combined. The supervisor and Chief Medical Officer reviewed the final list of themes and modifications to the module were made. The themes were categorised into items and divided into eight sessions.

5.2.1.3 Yoga module for SUD

A yoga module for SUD to manage SUD was previously developed and validate. However, it had not been tested for its feasibility. Tp develop the module, traditional yoga literature [15–17] and contemporary yoga texts [18,19] were consulted, and research studies were searched via Google Scholar and PubMed using the keywords "yoga", "*prāṇāyāma*", "meditation", "substance use", "addiction", "relapse" and "craving". Following a discussion with yoga experts, the yogic practices which may directly or indirectly manage SUD and its related symptoms were selected. The module was validated with the participation of 30 experts by using the Content validity ratio (CVR) method.

### 5.2.2 Phase 2 Validation of the Integrated Yoga Module for SUD (IYMSUD) [Figure 4]

**Figure 4: Illustration of Phase 2**

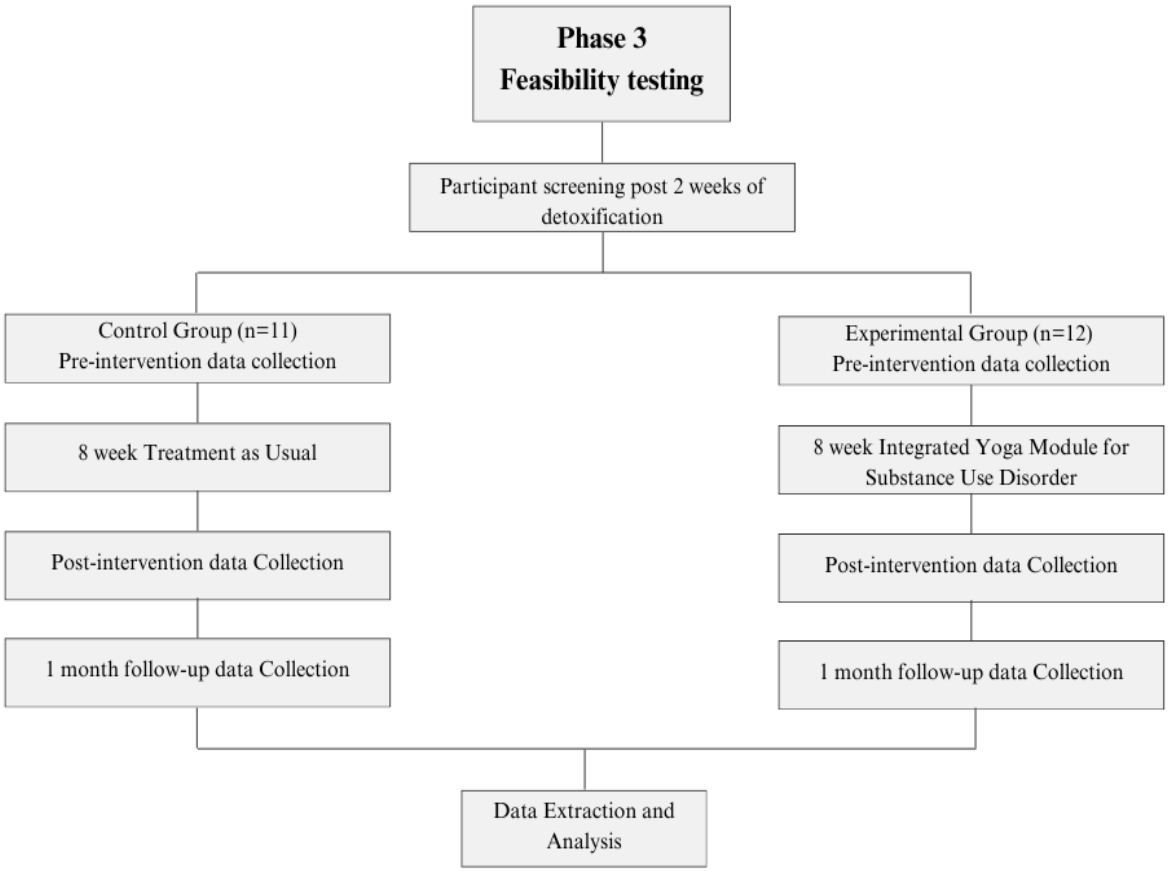



For the Integrated Yoga Module for SUD (IYMSUD) validation, quantitative and qualitative inputs were gathered from the experts after obtaining their informed consent. To assess the validity of the module, 36 experts from the fields of psychology, psychiatry, rehabilitation, and yoga therapy were contacted, out of which, 17 completed the module validation. The quantitative inputs were collected using the Delphi method, an inductive method of inquiry. Three iterations were carried out until saturation of data. The experts ranked the usefulness of each item and the entire module on a scale of 1 to 3 (1-not necessary, 2-useful but not essential, 3-essential). Experts' comments on the duration of the yoga session and the sequence of yoga

practices were taken. Based on the responses from the first batch of experts, the module was modified and sent for a second round of validation with a new batch of experts to avoid the primacy effect. A similar process was followed for the third round of iteration with another set of experts. The data collection was concluded at the third iteration as data saturation was achieved. We assured that there is no interaction between responder and interviewer to avoid bias Bergelson, I., Tracy, C., & Takacs, E. (2022).

### 5.2.3 Phase 3 Feasibility testing of Integrated Yoga Module for SUD (IYMSUD) for SUD (Figure 5)

**Figure 5: Illustration of Phase 3**




The design is an open label exploratory study which aim is to assess the feasibility and acceptability of participants in the Integrated Yoga module. Participants belonging to an 8-

week residential rehabilitation centre in Mauritius were evaluated by the Psychiatrist to confirm SUD severity, to assess whether the participants had withdrawal symptoms and to give medical clearance. Informed consent was taken based on the WHO template for informed consent for clinical studies. The same was available in English and Creole. The participants ensured that they are willing to:

- Commit to the research, i.e., adhere to the intervention regularly.
- Actively provide feedbacks and updates about their abstinence.

Participants were assured that they can withdraw from the research whenever required. They all underwent two weeks of detoxification and once the withdrawal phase was managed, they were allotted to the residential program. The rehabilitation centre adopted the 12-Step Program as an addiction recovery approach.

The intervention was taught by a Registered Psychologist who is also a yoga therapist. IYMSUD was carried out two days/week for eight weeks. The participants were divided into control group (Treatment as Usual-TAU) and experimental group (Yoga intervention + TAU). Throughout the TAU program, participants attended regular meetings and worked with a sponsor or mentor to support their recovery journey based on the 12-step Method. Sponsors, typically individuals with more experience in the program, offer one-on-one support, guidance, and accountability, helping participants navigate challenges and stay focused on their goals. Mentors facilitate group meetings, providing a space for sharing experiences and fostering a sense of community.

The first day consisted of one hour of physical practice and on the second day one hour of counselling was delivered. IYMSUD was taught as an add-on to their TAU. To ensure that there is no adverse effect of the practice, if the participant experiences any discomfort, they

were asked to stop the practice or were taught modifications. After each session, the yoga therapist asked each participant whether they had experienced any discomfort during the practice. In case of emergency, immediate medical assistance was to provided.

Data was collected pre-intervention, post-intervention and at 1-month follow up. After every session, participants rated their class on a scale of 1 to 5. At the end of the intervention, a semi-structured interview was carried out to gather the participant's acceptance, perception, feedbacks and suggestions for the Integrated Yoga Module experience.

## 5.3 SAMPLE SOURCE AND SELECTION

### 5.3.1 SAMPLE SELECTION

For this study, participants with a diagnosis of either New Psychoactive Drugs, or Opiates and Opioids or Polysubstance Use /Other Unknown substances were selected. Convenience sampling was adopted.

Adult male participants were selected as per convenience sampling from the Centre de Rahabilitation de Terre-Rouge, a residential rehabilitation centre in Mauritius. The center provides residential care for 9 weeks. The regular de-addiction program is based on the Twelve Step Method. To assess eligibility, participants were screened as per the DSM-V criteria for SUD by a Psychiatrist and they all underwent 10-14 days of detoxification.

Adult male participants were selected as per convenience sampling from the Centre de Rahabilitation de Terre-Rouge, a residential rehabilitation centre in Mauritius.

### 5.3.2 INCLUSION CRITERIA

The inclusion criteria for participants' enrolment in the study are as follows:

1. Individuals who have been diagnosed by the Psychiatrist with SUD.
2. Individuals who are males above 18 years old.
3. Individuals who are having medical clearance to participate.
4. Individuals who are fluent in either French/Creole/English.
5. Individuals who have undergone medically supervised detoxification at the center.
6. Individuals who areYoga naïve.

### 5.3.3 EXCLUSION CRITERIA

The exclusion criteria for the participants' enrolment in the study are as follows:

1. Individuals who have been diagnosed with psychotic disorders such as schizophrenia or bipolar disorder.
2. Individuals with acute withdrawal symptoms as assessed by the Psychiatrist
3. Individuals with acute suicidality or possibility of being of imminent danger to others.
4. Individuals needing intensive treatment due to high risk of relapse or continued heavy use, as determined by the Psychiatrist.
5. Individuals having undergone a recent surgery.

#### 5.3.1 Sample size

23 participants diagnosed with severe SUD were selected for this study. Sample size was determined based on the range given in the systematic review on yoga module development (Katla, 2022).

## 5.4 ASSESSMENT TOOLS

### 5.4.1 ANTHROPOMORPHIC ASSESSMENT

The quality of the research was assessed based on the Yoga Module Development and Validation Checklist (Katla et. al., 2022) The participants' blood pressure, Body Mass Index (BMI), respiratory rate, and *brhamari* time (exhalation with bee-sound) were taken. All assessments were implemented in French, as all participants were French speakers. The Vedic Personality of participants was assessed using the Gita Inventory of *guna* Personality, a standardised psychological tool that measures the three Gunas with a test-retest reliability of 0.60 and a confidence level of 99% (Das,1991). The *Questionnaire de motivation au traitement des toxicomanies* (QMTT) (Motivation to seek treatment questionnaire) assesses amotivation, external motivation, introjected motivation, and identified motivation and has satisfactory psychometric properties with alpha ranging from 0.62-0.75 (Simoneau,2005). The World Health Organization Quality of Life BREF (WHOQoL-BREF) which assesses physical, psychological, social relationships, and the environment health was administered. The French version of this scale has an internal consistency ranging from alpha=0.59 to 0.74 (Baumann, 2010).

i) Body Mass Index

The Body Mass Index (BDI) is a measure of body fat based on height and weight that applies to adult men and women. Alcohol, illicit drugs, and nicotine can affect appetite and body weight (Associations Between Body Mass Index and Substance Use Disorders Differ by Gender: Results from the National Epidemiologic Survey on Alcohol and Related Conditions). Studies of persons in treatment for substance use disorder (SUD) frequently report significant body weight gain and higher food consumption. It is unclear what psychological variables

might mediate a relationship between SUD treatment status and food selection (Food selection, food craving, and body mass index in persons in treatment for substance use disorder).

ii) Blood Pressure

Blood pressure is a measure of the force that the heart uses to pump blood around the body. Blood pressure is measured in millimetres of mercury (mmHg) and is given as 2 figures:

• systolic pressure – the pressure when your heart pushes blood out

• diastolic pressure – the pressure when your heart rests between beats

As a general guide:

• ideal blood pressure is considered to be between 90/60mmHg and 120/80mmHg

• high blood pressure is considered to be 140/90mmHg or higher

• low blood pressure is considered to be 90/60mmHg or lower

Substance abuse and hypertension are an important health concern, especially in adolescent and young adults presenting with elevated blood pressure and associated cardiovascular conditions. Illicit drugs including cocaine, marijuana, amphetamines, and methylenedioxymethamphetamine remain potential sources of acute or newly diagnosed hypertension (Ferdinand, 2000). Also, changes to certain neurotransmitters, which commonly occurs from drug abuse, may cause hypertension. In individuals with a pre-existing hypertension, the risk is compounded by the drug abuse (Grossman, 2012). Changes in blood pressure, especially spikes, are so commonly attributed to substance abuse, that labile blood pressure (sudden change from normal to elevated level) is considered a “red flag” for substance abuse. It has also been shown that withdrawal from certain drugs of abuse which do not normally pose a threat of hypertension during active abuse, may occur. The hypertensive effect

from substance abuse can produce a number of acute and chronic cardiovascular complications (Cruickshank & Dyer ,2009).

iii) Respiratory Rate

Drugs that are inhaled, smoked and injected drugs can lead to a variety of respiratory problems. People who use drugs are often unaware that when smoking cannabis or cocaine the smoke can cause lung damage.Pulmonary infections associated with heroin misuse include: community-acquired pneumonia, Lung abscess formation, Septic emboli with or without endocarditis, tuberculosis and bronchitis and Bronchiectasis. On the same line, cocaine has a number of effects on the respiratory tract as well. When sniffed or snorted, it may cause nasal mucosa to become ulcerated and perforated as a result of ischaemia, necrosis and infections. There are lines of evidence that suggest cannabis smoking may predispose people to respiratory malignancies. These include the presence of potential carcinogens in cannabis smoke and its deposition in the lungs (Rayner & Prigmore,2008).

To find the Respiratory Rate we assessed the number of respirations done by the participant in 1 minute. The respiration rate is the number of breaths a person takes per minute. The rate is usually measured when a person is at rest and simply involves counting the number of breaths for one minute by counting how many times the chest rises

iv) Bhrahmari

The calming effect of the Bhrahmari Pranayama helps in overcoming drug dependency . Practice of Bhrahmari Pranayama for 5–10 min continuously induces subjective feelings of mind refreshment and blissfulness and sometimes the subjects are believed to go to even meditative state (Vialatte et. al., 2009). All the studies directly or indirectly have found the

effect of Bhrahmari to have parasympathetic predominance and this was the basis for their results derived, namely; reduction in heart rate and BP, improvement in cognition, favourable EEG changes and reduction in stress levels (Kuppusamy et al. 2017), all of which might be affected in individuals with substance abuse. Yoga practices like Bhrahmari may be found beneficial for the improvement of the prefrontal cortex of the brain, self-control, sleep and overall stress relief in individuals with substance abuse (Sharma, 2019)

### 5.4.2 VEDIC PERSONALITY ASSESSMENT

Further, in the Bhagavad-Gita; guna indicates a specific behaviour style. Sattva is symbolized by purity, wisdom, bliss, serenity, love of knowledge, spiritual excellence and other noble and sublime qualities. Rajas is symbolized by egoism, activity, restlessness and hankering after mundane things like wealth, power, valour and comforts. Tamas is related to qualities such as bias, heedlessness and inertia, perversion in taste, thought and action. Ill health occurs if Rajas or Tamas become dominant and the individual gets habituated to either of these response patterns.

The Gita Inventory (GIN) is a standardized, psychological tool, and is based on the concept that there are three different levels of human existence in which the mind is always in a dynamic equilibrium between three types of response patterns, i.e, the Trigunas. This measure of the three Gunas contains 10 questions that have three response choices. This test has a test-retest of 0.60 with a confidence level of 99% and has been validated. This is a valid tool for identifying the type of personality (Das, 1991). The Creole translations through forward and back translation was made available as per the convenience of the participants.

### 5.4.3 MOTIVATION TO SEEK TREATMENT

SDT is a macro-theory of human motivation, emotion, and personality in social contexts. With its organismic perspective, SDT posits a natural tendency toward psychological growth, physical health, and social wellness that is supported by satisfaction of the basic psychological needs for autonomy, competence, and relatedness. Autonomy refers to the experience that behavior is volitional and reflectively endorsed, and is measured on the treatment self-regulation questionnaire. The Questionnaire de motivation au traitement des toxicomanies (QMTT) is a French-language questionnaire based on the theory of self-determination. It is made up of 15 items which covers amotivation; external regulation, introjected regulation and identified regulation. It has satisfactory psychometric properties with alpha raging from 0.62-0.75

### 5.4.4 WORLD HEALTH ORGANIZATION QUALITY OF LIFE BREF

WHOQOL-BREF are internationally validated and available in 30 languages, including French, which makes them generalizable to many populations. There are 26 items in this questionnaire which assesses four domains related to quality of life: physical health, psychological, social relationships and environment. It also includes one facet on overall quality of life and general health. The French version of this scale has an internal consistency ranging from alpha=0.59 to 0.74 (Baumann et. al., 2010).

### 5.4.5 DEMOGRAPHIC DETAILS

The participants' demographic details was taken at baseline. This includes family history, socio-economic status, marital status, medical history including drug intake frequency, addiction history, frequency of relapse

### 5.4.6 DIAGNOSIS OF ADDICTION SEVERITY

A Psychiatrist assessed the addiction severity of participants by using the Diagnostic and Statistical Manual of Mental Disorders, 5th Edition. The participants' addiction severity was categorised depending on the number of criteria they fulfil. Two or three criteria indicate mild SUD, four to five moderate and six or more severe SUD. In addiction the individual experiences significant loss of self-control by taking the drug out of compulsion despite not wanting to (American Psychiatric Association, 2013).

### 5.4.6 YOGA MODULE DEVELOPMENT AND VALIDATION CHECKLIST

The quality of the module development and validation process was assessed based on the Yoga Module Development and Validation Checklist. It has 23 items related to three domains namely: yoga module development, yoga module validation, yoga module feasibility. Score range: 0 to 7=Low quality, 8 to 16=Moderate quality, 17 to 23=High quality

### 5.4.6 SESSION RATING

Session rating system was implemented to assess participant experiences after each session. Participants were asked to rate their overall experience and indicate whether any negative effects were encountered by selecting "Yes" or "No." This straightforward approach allowed for immediate feedback to be gathered, enabling timely adjustments and ensuring the intervention's effectiveness while monitoring any potential adverse outcomes.

### 5.4.7 SEMI-STRUCTURED INTERVIEW AT FOLLOW UP

Following the YBC intervention, semi-structured interviews were conducted to gather detailed feedback from participants. The interviews aimed to determine whether participants continued to practice yoga, the specific types of yoga they still engaged in, the frequency of their practice,

and to collect any overall remarks or reflections on their experience. This information was crucial for assessing the lasting impact of the intervention and understanding participants' ongoing yoga habits.

### 5.5 ETHICAL CONSIDERATION

This study has received ethical approval from the Institutional and the Ministry of Health and Wellness. The Institutional Ethics Committee (IEC) of Swami Vivekananda Yoga Anusandhana Samsthana (Deemed-to-be University under Section 3 of UGC Act,1956) was received on 06/03/2021;Certificate Reference number: RES/IEC-SVYASA/194/202. The National Ethics Committee Decision – Republic of Mauritius, Ministry of Health and Wellness was received on 06/08/2021;Reference number: MHC/CT/NETH/2021 V3.

Details of the study was explained to each participant and verbal as well as written consent was taken. The consent form was available in English, French and Creole languages. The participants were explained how the study can be beneficial to them.

### 5.6 DATA EXTRACTION AND ANALYSIS

For the qualitative data, extraction was done using a coding system which will identify various themes for the module development and for the feedback semi-structured interview. Lawshe's Content Validity Ration (CVR) was used for statistical evaluation of the items. The analysis of the experts' responses was performed using Lawshe's Content Validity Ratio (CVR) formula; CVR = (Ne-N/2)(N/2), where N is the total number of experts and Ne is the number of experts who believe the practice is essential (Lawshe,1975). Items with a cut-off CVR score $\geq 0.33$ were selected for the yoga module for SUD and a cut-off CVR score $\geq 0.99$ for the YBC module

for SUD. For the module feasibility testing, a paired sample t test and independent sample t test was done to assess the data.