A randomized control trial to study the effectiveness of the Mobile Functional Cognition Program for persons who have substance abuse

1. Introduction

Substance use disorder (SUD) is a community health issue that influences society from multiple personal, social, and financial perspectives. According to the Narcotics Division, Security Bureau (2020), there are 4,129 reported drug abusers in the first quarters of 2020 in Hong Kong. There is also a trend of increasing younger drug abusers (HKSAR, 2019; Legislative Council Secretariat Research Office, 2019). It is known that SUD affects cognitive and general everyday functioning in individuals (Leung, 2015). The extent and kind of impact may vary depending on the type of substance use.

Previous evidence manifested extensive and persistent cognitive alteration in many individuals diagnosed with SUD (Goldstein and Volkow, 2002). People who have chronic heroin use are associated with limited impairments in various cognitive abilities: memory, cognitive impulsivity, non-planning impulsivity, compulsivity, and decision-making (Tolomeo et al., 2020). Abusers of ketamine have been associated with deficits in working and episodic memory (Morgan & Curran, 2012). Prolonged ketamine use selectively impaired multiple domains of frontal and medial temporal functioning, possibly specific to verbal information processing (like verbal fluency and verbal learning), as well as cognitive processing speed (Chan et al, 2013). Frontal-executive functioning deficits were present in amphetamine and cocaine users (Rogers et al., 1999; Fernandez-Serrano, 2011). There are also reports showing that amphetamine abusers would experience prominent impairment in visual-spatial memory and processing (Mcketin and Mattick, 1997; Ornstein et al., 2000), spatial planning, and pattern recognition memory (Ersche et al., 2006). Some studies found that chronic use of cocaine could lead to impairments in short-term verbal memory, visuospatial ability, and working memory (Sudai et al., 2011).

A few reports argued that brain neuroplasticity could enable recovery in stimulant users' cognitive performance, mainly in the short-term users (Morgan et al., 2010; Vonmoos et al., 2014). However, efforts to alleviate these individuals' cognitive deficits are still crucial. Valls-Serrano et al. (2016) used Goal Management Training and Mindfulness Meditation to help polysubstance users to improve their working memory. Rezapour et al. (2019) applied a cognitive rehabilitation treatment to improve executive functions in people with opioid use disorder. Kiluk et al. (2017) use Cognitive Remedial Treatment and Contingency Management to enhance the cognitive function of individuals with substance abuse. Nevertheless, the number of studies is still limited, and there has been no particular program in Hong Kong.

In this connection, occupational therapists in United Christian Hospital had launched a two-year pioneer program, namely Mobile Functional Cognition Program (MFCP), since July 2015. The target service users who had substance use disorder were found to have preliminary improvements in cognitive and community functioning in general upon completing the program. In this study, we conducted a randomized controlled trial to investigate the effectiveness of the MFCP on the cognitive abilities and community functioning of substance abusers. We hypothesized that the study participants who went through the MFCP (in the experimental group) would improve their cognitive and everyday functioning compared to those who received social activities (in the control group).

2. Method

2.1. Study design

This study employed a multi-center randomized controlled trial conducted between 1 September 2017 and 31 January 2021. Participants were randomized into control or experimental groups. The experimental group received the MFCP while those in the control group went through social activities.

2.2. Participants

We recruited service users at the Counselling Centers for Psychotropic Substance Abusers (CCPSAs), the Drug Treatment and Rehabilitation Centers (DTRCs), and the Methadone Clinic and Substance Abuse Clinic at the United Christian Hospital. Active abusers with a history of substance abuse in the past 12 months who were willing to receive assessment and training in functional cognition were recruited by referral from the centers' staff. Individuals who were not mentally and medically stable were excluded from the study..

Based on our pilot in 2015-2017, we assume the effect size would be 0.4. The sample size was estimated as 50 in each arm by the G*Power (Faul et al., 2007). In considering the potential attrition, we recruited and randomized 134 individuals with substance abuse. The final sample for data analysis included 53 in the experimental group and 57 in the control group. Details can be referred to the Consort diagram and Table 1.

2.3. Measures

2.3.1. Sociodemographic data

The participants' sociodemographic information, including sex, age, education level, and duration of substance use, were obtained and entered into a database.

2.3.2. Cognistat (Neurobehavioral Cognitive Status Examination - NCSE)

The Chinese Cognistat (Chan et al., 1999) was used to assess the participant's cognitive functioning. It is a cognitive screening instrument that assesses the five major ability areas: language, spatial skills, memory, calculations, and reasoning. It was widely adopted as a tool to detect cognitive impairment and measure treatment outcomes on substance abusers (Alessi et al., 2006, Meek et al., 1989, Schrimsher et al., 2007).

2.3.3.Canadian Occupational Performance Measure (COPM)

The Chinese COPM (Chen et al., 2002, Pan et al., 2003) was used to assess the participants' self-perceived everyday functioning. It is a semi-structured interviewing tool for measuring all life areas, including self-care, leisure, and productivity. Individuals' perceptions of the importance and performance are rated on a 10-point Likert scale. The COPM is proven to be a valid, reliable, practical, and responsive outcome measure (Carswell et al., 2004).

2.4. Interventions

2.4.1. MFCP in the experimental group

Participants in the experimental group went through at least 4 but at most 8 sessions of MFCP. It included psychoeducation, teaching strategies for coping with cognitive deficits, and CogniPlus training.

CogniPlus is a computerized training system based on a function-specific intervention approach developed by SCHUHFRIED (https://www.schuhfried.com/cogniplus/). It adopts a realistic design that resembles some actual daily activities, such as driving and planning daily schedules. The system would automatically adapt the training level to suit the participants' performance levels. Cogniplus training covers attention, visual-field training, working memory, long-term memory, executive functions, spatial processing, and visuomotor skills. CogniPlus is available in different languages, this project employed the Chinese (Taiwan) version by which participants can train in his/her language.

Each MFCP training session lasted for 90 mins. Participants were provided with paper and pencil homework assignments after each session and were required to hand them in the next session.

2.4.2. Social activities in the control group

Participants in the control group received at least 4 but at most 8 sessions of social activities. Each social activities session involved 3 to 6 participants and lasted for 90 minutes. The curriculum of the control group was decided based upon the characteristics and interests of each group of participants. A brief discussion was held at the end of each session to determine the content of the next session.

The participants were allowed to choose a group activity from the following three categories:

(1) Art and craft activities:

- Zentangle – It is a leisure activity creating beautiful images with dots, lines, and simple curves. The therapist provides samples of Zentangle patterns from which the participants can make use to create their products. After making the patterns, participants are encouraged to share their views and feelings in the production process.
- Origami – It is a kind of Japanese style of folding paper sheets into decorative objects. Sample sculptures are provided so that the participants can imitate or they may create their products. It is used for fun and enjoyment in the process of creation. Participants are encouraged to share after the making of the sculptures.
- Nagomi Art – It uses pastels to produce transparent, gentle, warm, and heart-touching pictures. Participants are provided with samples to facilitate their pattern creation. Alternatively, they can design their patterns. After the art production, participants are encouraged to share their joy during the activity.

(2) Board games:

- DIXIT – It is an imaginative storytelling game for social and fun. Each participant takes a turn to be the storyteller and looks at one of six picture cards based on which they make up a sentense. The other participants then guess the card that best matches the sentence. If nobody or everybody finds the correct card, the storyteller scores 0, and each of the other players

scores 2. Otherwise, the storyteller and whoever finds the correct answer scores 3. Players score 1 point for every vote for their card. The game ends when the deck is empty or if a player scores 30 points. In either case, the player with the most points wins the game. For further details, please refer to https://www.jollythinkers.com/products/dixit.

- GeistesBlitz – It is a reaction game for fun, identifying the correct match of shape and color as fast as possible. Five wooden items sit on the table waiting to be caught (a white ghost, a green bottle, a cute grey mouse, a blue book, and a comfortable red chair). Each card in the deck shows pictures of two objects, with one or both objects colored the wrong way. With all players playing simultaneously, someone reveals a card, and then players grab the correct object. The first player who catches the correct object will keep the card and then reveals the next card from the deck. If a player finds the wrong object, one must discard one card previously collected. Once the card deck runs out, the game ends, and whoever has collected the most cards wins. Please refer to https://boardgamegeek.com/boardgame/83195/ghost-blitz for details

(3) Mindfulness practice or relaxation exercises:

- Mindful practice – It is a kind of meditation practice. Participants sit in a comfortable and calm position. They are then advised to pay attention to their bodies, breath, and mind. Groupmates need not judge themselves or cling to the content of their thoughts. In the group, participants are encouraged to appreciate and let go of any thoughts in their mind.
- Health qigong baduanjin – It is a form of traditional Chinese qigong exercise. It aims to achieve a harmonious interplay between symmetrical physical postures and movement, mind, and breathing. The activity is adopted for a relaxation purposes. A musical soundtrack is played, and the therapist, trained in baduanjin, guides the participants in doing the exercise.

2.5. Procedures

2.5.1. Recruitment and randomization

People referred from the study centers were explained by the investigators about the research project and were provided with written consent forms and research information. Consented participants were randomized into the experimental group or control group using block randomization procedures described by Kang et al. (2008) to generate similar numbers of participants between groups within a small sample size clinical trial (i.e., n equals or smaller than 60) from various centers. Blocks were randomly chosen by lottery to determine the assignment of all participants in each cohort of referral.

2.5.2. Data collection

Corresponding intake and assessment procedures were conducted by trained occupational therapists.

2.5.3 Assessments

Before the training program's commencement, each participant was assessed on their drug abuse pattern within the last 30 days in the community, cognitive functioning, and everyday functioning. After completion of the program, each participant was once again assessed on their cognitive and everyday functioning.

2.6. Statistical analysis

Comparisons of baseline sociodemographic between the experimental and control groups were assessed by the independent sample t-test, Mann Whitney U, and chi-square test as appropriate. Repeated measure analysis of variance (ANOVA) was used to evaluate the treatment effect.

The RCT groups were entered as between-group factors, whereas repeated outcome scores were treated as within-group factors. A post hoc Schéffe test was used to compare the between and within-group differences.

2.7. Ethical considerations

The study protocol complied with the ICH-Good Clinical Practice and was approved by the Research Ethical Committee of Hospital Authority. All individuals recruited have their right to self-determinate and the right to make informed decisions regarding participation in the research at any time. The MFCP mainly adopts psychoeducational and cognitive remedial approaches conducted by suitably trained investigators and did not involve invasive treatment. Data collection and retention strictly followed the information and security privacy policy imposed by the Hong Kong Hospital Authority.

3. Results

Table 1 shows the sociodemographic data of the study sample. As can be seen, the two groups did not differ in terms of sex, age, and education level.

Table 2 shows the cognitive and functional outcomes of the study participants. As can be seen, there was no difference in baseline NCSE and COPM scores across the groups.

Referring again to Table 2, the outcome x group interaction term in the repeated measure ANOVA reflected that the MFCP (in the experimental group) had no greater effect over the social activities (in the control group). The outcome x group interaction terms for NCSE, COPM performance, and COPM satisfaction had *p*-values of .759, .844, and .959, respectively.

However, the post hoc Schèffe test revealed that the MFCP had significantly improved the experimental group's NCSE and COPM scores (with p-values of < .001, .020, .007). Interestingly, a

similar pattern occurred in the control group with *p*-values of .002, .032, and .004. Figure 2 depicts the cognitive and functional scores of the participants.

The effect sizes of outcome improvement of the MFCP (in the experimental group) over the social activities (in the control group) are summarized in Table 3. As shown, the MFCP showed more improvement than the social activities with Cohen's *d* values of NCSE, COPM performance, and COPM satisfaction 0.07, 0.04, and -0.01, respectively.

4. Discussion

We have compared the treatment effect of the MFCP with social activities in improving individuals' cognitive and functional abilities with substance abuse. In contrast with our hypothesis, the repeated measure ANOVA outcome x group interaction terms did not reach statistical significance. Interestingly, the participants in both the experimental and control group showed improvement in their cognitive and everyday functioning after treatment.

In our earlier pilot project in 2015-2017, we found that the participants who went through the MFCP improved in their cognitive abilities, but there was no control group for comparison. In this study, the individuals who received MFCP did not show statistically significant better improvement than those who went through social activities. Khemiri et al. (2019) and Manning et al. (2019) reported that cognitive training did not produce substantial results. There still needs more research on effectiveness of cognitive training for SUD.

This study's social activities also increased the participants' cognitive and functional outcomes though in a lesser magnitude than the MFCP. There have been reports of a positive direct effect of social activities and social relationships on cognitive functioning (Cohn-Schwartz, 2020; Kelly ME et al., 2017; Li H et al., 2020). That could explain our observation on the positive change in the control group.

Although both experimental and control groups' outcomes demonstrated positive change, the MFCP exhibited a greater effect size than the social activities. We do not know if the MFCP would show a greater improvement rate because we did not employ a time-series study design. Future research with the said methodological refinement(time-series study) may help verify the issue.

The study has certain limitations. The investigators (therapists) had to visit the various centers to carry out the project. Although we successfully controlled the experimental conditions in our service sessions, we could not totally rule out the possibility that some of the respondents had exchanged their views on some of the questions through other channels. For example, we received reports from DTRC staff that some control group participants asked their roommates and completed the experimental groups' assignments. That would impose a confounding effect on the research. Furthermore, we did not apply a longitudinal study design. With these limitations, future studies would be recommended and measures to forestall collusion of response could improve the validity of respondents' feedback.

The research on cognitive training for SUD is still limited, and future study is warranted. The MFCP, which has been refined over the years, is practical and easy to apply in clinical practice. Further evidence on cognitive training for SUD is necessary.

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Table 1. Sociodemographic data of the research participants

	Experimental Group (n=53)	Control Group (n=57)	Comparison	
			Statistics	*p*-values
	Count (%)	Count (%)		
Male	24 (45.3%)	25 (43.9%)	0.023[a]	.881
	Mean (SD)	Mean (SD)		
Age	35.4 (10.9)	37.1 (11.2)	1287[b]	.296
Education (years)	8.9 (2.2)	9.2 (2.4)	619[b]	.779

Remarks: [a]Chi-square; [b]Mann-Whitney *U*

Table 2. Clinical data of the research participants

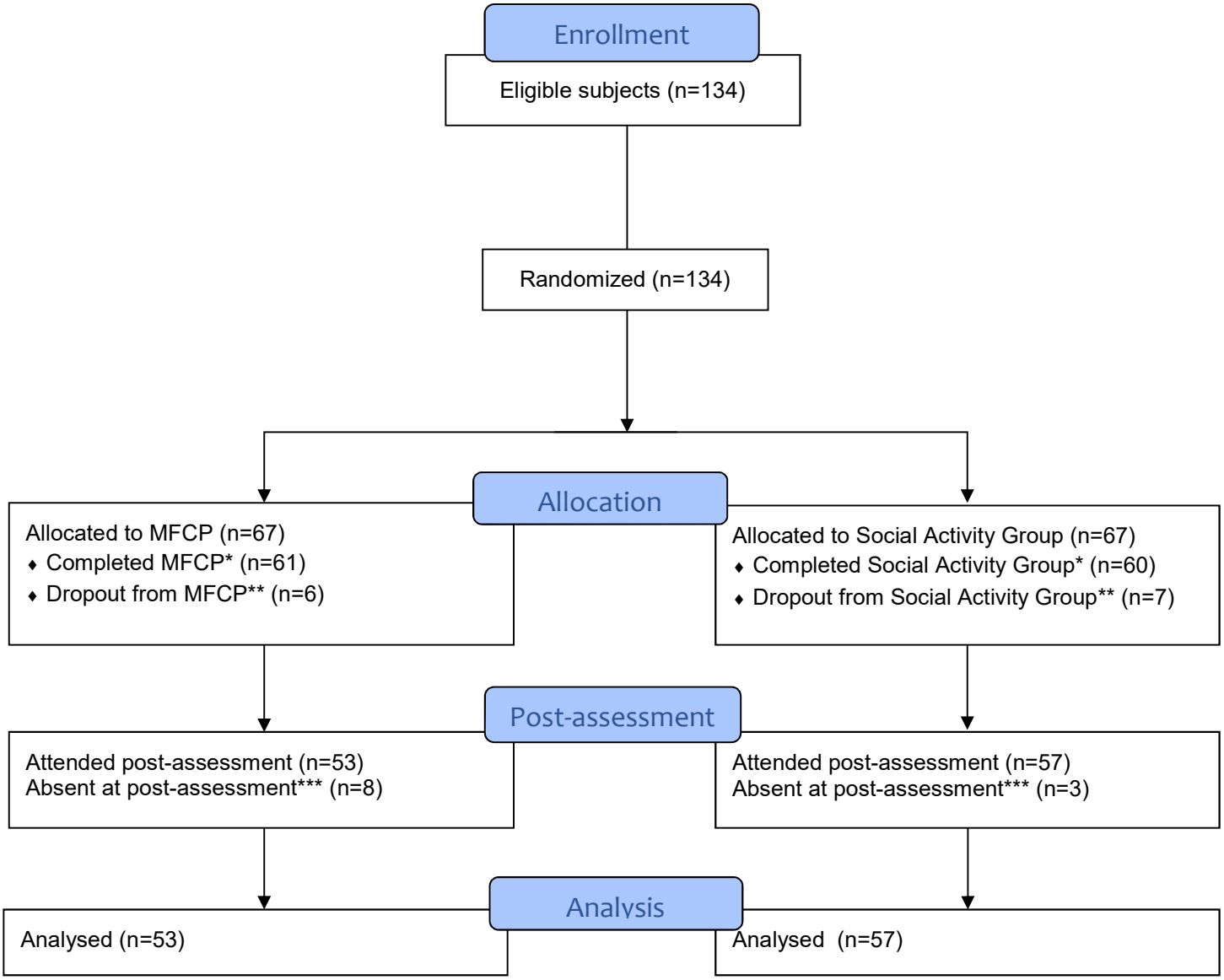
	Experimental Group (n=53)		Control Group (n=57)		Repeated measure ANOVA (Outcome x group)	Post hoc Schèffe test		
	At baseline	After treatment	At baseline	After treatment		Experimental vs control at baseline	Pre vs post in Experimental group	Pre vs post in Control group
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	*F* (p-value)	*t* (p-value)	*t* (p-value)	*t* (p-value)
NCSE	73.6 (6.60)	76.5 (4.7)	72.8 (6.0)	75.4 (6.0)	0.09 (.759)	0.73 (.913)	4.26 **(< .001)**	3.97 (**.002**)
COPM Performance	81.8 (19.6)	88.5 (16.2)	81.1 (15.5)	87.2 (13.6)	0.04 (.844)	0.24 (.996)	3.19 (**.020**)	3.03 (**.032**)
COPM Satisfaction	81.6 (20.6)	89.4 (16.6)	79.9 (17.4)	87.8 (14.7)	0.003 (.959)	0.52 (.965)	3.56 (**.007**)	3.76 (**.004**)

Remarks: NCSE = the Neurobehavioral Cognitive State Examination; COPM = Canadian Occupational Performance Measure

Table 3. Effect size of experimental group against control group

Improvement	Experimental Group (n=53)	Control Group (n=57)	Effect Size of experimental against control
	Mean (SD)	Mean (SD)	Cohen's *d*
NCSE	2.96 (5.34)	2.61 (4.60)	0.07
COPM Performance	6.70 (14.3)	6.12 (16.1)	0.04
COPM Satisfaction	7.77 (14.7)	7.93 (17.0)	-0.01

Figure 1. Consort Diagram of the study



Remarks

*Completion of intervention (MFCP or Social Activity Group) was defined by attendance >50%

**Reasons for dropout included:

1) premature or unplanned discharge from detox settings; 2) admission to hospital; 3) time clash with other activities or duties; 4) change in physical or mental states; and 5) refusal to continue intervention

***Reasons for absence at post-assessment:

1) premature or unplanned discharge from detox settings; 2) time clash with other activities or duties; and 3) sick leave

Figure 2 Plots of the NCSE and COPM scores of the study participants