

Stop&Go – Promoting healthy lifestyles during inpatient detoxification treatment: rationale, intervention design, methodology

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STOP&GO – PROMOVRIENDO VIDAS SALUDABLES DURANTE EL TRATAMIENTO DE DESINTOXICACIÓN: JUSTIFICACIÓN, DISEÑO, METODOLOGÍA

KEYWORDS: Exercise motivation, substance use, healthy living, physical activity, autonomy support, self-determination theory.

ABSTRACT: Exercise could help in the treatment of substance addictions. However, there is a lack of programs promoting a healthy and physically active lifestyle for patients requiring inpatient detoxification treatment. We present the protocol of an intervention program with such characteristics, namely Stop&Go. Stop&Go includes two different phases. Phase I is aimed at understanding the variables related with adherence to healthy lifestyle interventions. Patients with substance use disorders will be invited to participate in focus groups (Study1) and to respond to questionnaires assessing variables related to exercise and healthy habits (Study2). Phase II will use the knowledge obtained in Phase I to develop and evaluate an intervention to promote healthy and physically active lifestyles for patients admitted to an inpatient detoxification center. The intervention will also be based on Self-determination theory postulates. Patients will participate in four practically-oriented training sessions, focused on (1) physical activity and exercise, (2) nutrition and oral hygiene, (3) sleep habits and self-care, and (4) smoking cessation. In addition, the entire inpatient detoxification center will be adapted to encourage autonomous physical activity/exercise and to reinforce the ideas presented in the psychoeducational sessions. It is expected that, compared to a control group, patients engaged in the Stop&Go intervention will show: (a) higher scores in exercise-related variables (e.g., autonomous motivation), (b) better mental health status, and (c) greater knowledge regarding healthy and physically active lifestyles.

Considering the benefits that physical activity could be bring to general population (World Health Organization, 2010), researchers in mental health have develop interventions promoting physical activity and the adoption of healthy habits (e.g., Baker et al., 2011). In patients with substance use disorders, it is assumed that exercise could be a useful tool in the treatment of addictions (e.g., Linke and Usher, 2015). In this sense, interventions have been developed to change the lifestyle of patients involved in residential or therapeutic community treatments (e.g., Keane et al., 2016). However there is a lack of programs targeting the healthy and physical activity habits of

patients in early abstinence (i.e., during detoxification treatment).

A recent study by Beiter, Peterson, Abel and Lynch (2016) pointed out that exercise during early abstinence could provide protection against cocaine relapse. The authors argued that even a small amount of exercise during early abstinence could be effective to reduce substance-seeking behaviors and substance relapses. Thus, a challenge for practitioners would be developing an attractive intervention program that helps early abstinent patients engage in healthy and active lifestyles during their admission to detoxification treatments (e.g., in inpatient

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detoxification centers). This program should also help patients maintain this lifestyle during the process of dishabituation and reintegration into society.

Adherence to interventions that promote physical activity and exercise has been widely studied from the Self-determination theory perspective (SDT; Deci and Ryan, 1985, 2000). According to SDT, social contexts play a key role in psychological needs fulfillment, which in turn impacts on people's regulations to engage in or disengage from a particular activity (Deci and Ryan, 2000). The behavioral regulations could be ordered along a continuum of self-determination (see Ryan and Deci, 2000; Ryan, Williams, Patrick, and Deci, 2009). According to SDT, the clinical staff could stimulate patients' empowerment and motivation to change their lifestyle by giving them tools and support during their process of recovery. The theory emphasizes that therapists (or clinical staff) should support patients' autonomy during the process of therapy, as autonomy support has been related to positive outcomes of treatment (Ryan and Deci, 2008).

As described above, there is a lack of programs addressing patients' healthy lifestyles during early abstinence. To address this gap in the literature, we outline the design and rationale of Stop&Go, an intervention program aimed at promoting changes towards healthy and physically active lifestyles for patients in early substance abstinence admitted to an inpatient detoxification center. It is hypothesized that, at the time of discharge, patients in the Stop&Go group –compared to a control group– will show: (a) higher autonomous motivation towards exercise and greater intention to be physically active, (b) better mental health status (e.g., psychological well-being), and (c) greater knowledge regarding healthy and physically active lifestyles.

Method

Overview and study design

Figure 1 presents an overview of our program, which includes two different phases. Phase I is aimed at better understanding our target population and the variables related with their adherence to healthy lifestyle interventions. Patients with substance use disorders will be invited to participate in focus groups (FGs; Study1) and to respond to questionnaires assessing variables related to exercise and healthy habits (Study2). Phase

II will use the knowledge obtained in Phase I to develop and evaluate a skill-based intervention to promote healthy and physically active lifestyles (i.e., the Stop&Go intervention). The protocol of this program has been approved by the authors' Institutional Research Ethics Board and has been registered in Clinical Trials (NCT03055351).

Phase I, Study 1: Qualitative study

Participants

Participants will include both sedentary and physically active male and female patients that meet the following inclusion criteria: (a) meeting DSM-5 criteria for substance use disorder (American Psychiatric Association, 2013); (b) request for treatment primarily aimed at substance detoxification, (c) voluntary admission to an inpatient detoxification center (i.e., inpatients) or to an outpatient resources (i.e., outpatients), and (d) age \geq 18 years old. In addition, Study 1 will include a sample of experts in different topics of interest for this research (e.g., physicians, physical activity psychologists) that will participate in an experts' FG.

Instruments

On the one hand, the experts' FG guide will encourage a discussion regarding (a) patients' adherence to and participation in health-promoting interventions, (b) efficacy of those programs, and (c) health-promoting psychoeducational training sessions. On the other hand, patients' FGs guide will target the following topics: (a) patients' adherence to health-promoting interventions, (b) characteristics of such programs (e.g., content, structure), and (c) detoxification centers as promoters of healthy and physically active habits. A few changes will be introduced depending on whether FGs are conducted with physically active or sedentary patients. FG guides are available from the first author upon request.

Procedure

First, we will conduct a pilot focus group to review the FG guide and its development. Then, we will conduct one FG with experts and at least four FGs with outpatients and inpatients each. Among these, at least two FGs each will be conducted with physically active inpatients, physically active outpatients, sedentary inpatients and sedentary outpatients. The specific number of FGs will be determined by the point at which data saturation is been reached. Consistent with previous research (e.g., Aelterman et al., 2013), around six patients will participate in each FG. Both sexes will be represented in each focus group.

During their hospitalization, those inpatients that meet the above-mentioned inclusion criteria will be randomly requested to participate in the Study. Focus groups will be led by the first author with the assistance of another researcher and will follow the FG guides described above. Prior to participation, all participants will receive information about the purpose of the study and will give written informed consent.

Data analysis

Focus groups will be recorded and transcribed verbatim. We will give participants the opportunity to review the transcription of their comments and to introduce changes if required. Then, we will conduct a hierarchical content analysis (Sparkes and Smith, 2014).

Phase I, Study 2: Quantitative study

Participants

The sample will consist of inpatients with substance use disorders, voluntarily admitted to an inpatient detoxification center. A minimum of 150 inpatients will be included in the study. Since more men than women require detoxification treatment, our sample is expected to follow the same sex distribution. Participants will meet the same eligibility criteria described above. According to previous data, it is expected that inpatients' main substance of use will be: (1) alcohol, (2) cocaine, and (3) opioids.

Instruments

Details of the measures assessed in Study 2 are presented in Figure 2. The key variables will be psychological, including measures related to patients' exercise, ill-being and well-being. More information regarding the specific instruments is available from the first author upon request.

* Healthy lifestyle knowledge will be measured with 10-item multiple-choice tests created *ad-hoc*. Four different models were developed and participants will randomly respond to two of these models (i.e., admission and discharge). Each model includes items about physical activity, exercise, nutrition, oral hygiene, sleep habits and self-care. ** To perceive changes, all psychological instruments will measure states.

Procedure

All patients admitted for treatment in an inpatient detoxification center will be invited to participate. Participants will receive information about the purpose of the study and will give written informed consent. Data will be collected at the moment of

patients' admission, during their hospitalization and at the moment of discharge.

Data analysis

We will conduct confirmatory factor analyses for each instrument and we will assess scale reliability. We will also test descriptive comparisons between (a) sexes, (b) levels of physical activity and (c) main substance uses, using chi-square tests and independent samples t-test. Regression modeling will be then used to analyze the variables related to inpatients' exercise. In all tests, $p = .05$ will be used as the level of significance.

Phase II: Stop&Go Intervention

Participants

First, a pilot study with at least 30 inpatients will be conducted. Then, two groups will be included to test the Stop&Go Intervention: (a) intervention group and (b) control group. The intervention group will participate in the Stop&Go intervention. The characteristics of all participants and the eligibility criteria will be identical to the ones described in Study 2 (Phase I). The data collected in Study 2 (Phase I) will serve as control group data at this stage. A minimum of 100 inpatients will be included in each group.

Instruments

The measures and the process of data collection followed in Phase II will be identical to Study 2 (Phase I; see Figure 2). In addition, a measure of inpatients' satisfaction with the intervention will be included at this stage. The information collected with this instrument will be used to adapt and improve the Stop&Go intervention.

Procedure

Overview of the Stop&Go intervention. In Phase II we will develop, deliver and evaluate the Stop&Go intervention. This intervention will be based on both the results obtained in Phase I and the postulates of SDT (Deci and Ryan, 1985, 2000). As can be observed in Figure 1, the Stop&Go intervention will be structured in two levels: one specific (i.e., Educate) and one global (i.e., Motivate). In the Educate level we will use skill-based psychoeducative training sessions to promote healthy and physically active lifestyles among inpatients. The structure of these sessions will include: (a) a brief introduction presenting the key aspects of a specific topic (e.g., exercising at home), and (b) a set of skills and tools to transfer those concepts to the reality of patients' life. Four different psychoeducational training

sessions will be delivered: (1) physical activity and exercise, (2) nutrition and oral hygiene, (3) sleep habits and self-care, and (4) smoking cessation.

The Motivate level, on the other hand, aims at developing a global change in the philosophy that exists at the detoxification center, through: (a) staff's promotion of healthy and physically active lifestyles; (b) improvement of center's facilities to help patients integrate physical activity into their everyday lives; (c) reminders of the knowledge acquired during the psychoeducational training sessions via information panels; (d) creation of the "Stop&Go Hour", to encourage patients' autonomous physical activity, and (e) group training sessions with a fitness instructor. Additionally, at the time of inpatients' discharge, participants will receive a care plan (a) highlighting the key aspects of a healthy and physically active lifestyle and (b) describing personalized guidelines and resources to help them stay active in their everyday life. Further information regarding the Stop&Go intervention can be observed in Figure 3.

Pilot study and Stop&Go intervention. Prior to the delivery of the Stop&Go intervention, we will conduct a Pilot of the intervention. The purpose of this step is to test the whole intervention, including both Educate and Motivate levels. Using all the information gathered at this stage (e.g., inpatients' suggestions for improvement), the research team will propose changes to improve the main Stop&Go intervention.

Data analysis

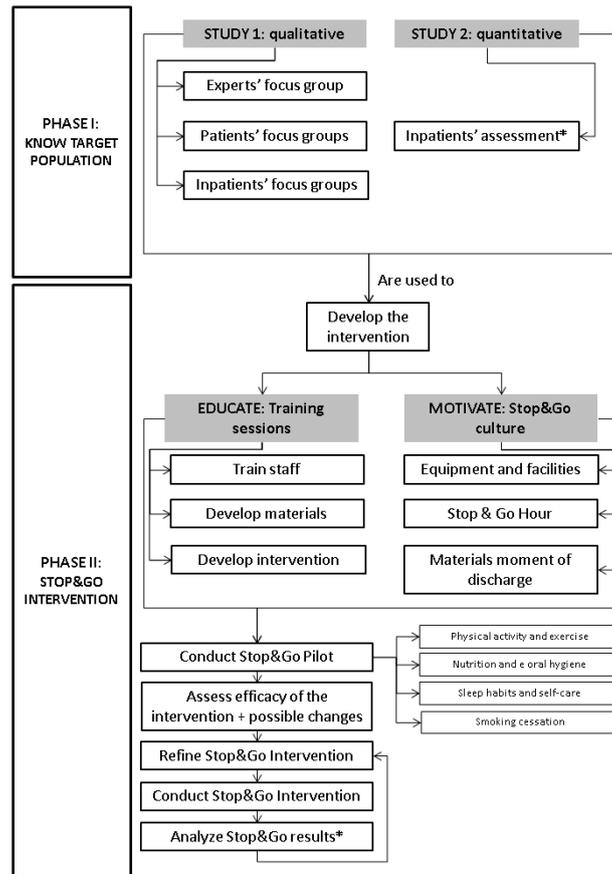
Preparatory data analysis will follow the same rationale described in Study 2 (Phase I). Then, we will test the efficacy of the intervention to: (a) Increase inpatients' autonomous motivation to exercise and inpatient's intention to be physically active; (b) Improve inpatients' mental health indicators (e.g., anxiety) and (c) Improve inpatients' knowledge regarding healthy and physically active lifestyles. Repeated-measures ANOVA will be conducted for each dependent variable, in order to evaluate whether the intervention has significant effects. Correction for multiple comparisons will also be used.

Discussion

Stop&Go is an SDT intervention program aimed at promoting changes towards healthy and physically active lifestyles for patients with substance use disorders admitted to an inpatient detoxification center. The main strength of Stop&Go is the combination of viewpoints included in its development (i.e., intervention led by an interdisciplinary team and based on patients' needs). Specifically, the inclusion of patients' perspective will probably make the intervention closer to their reality, which is expected to produce positive results.

However, some expected limitations should be highlighted. First, it has to be noted that the detoxification treatment alone is expected to generate positive consequences for inpatients. Thus, the challenge will be to establish which changes are attributable to the Stop&Go intervention (i.e., the actual effect of the intervention) and which depend on the process of treatment alone. To do so, the simple effects of each group level will be calculated and compared (Heck, Thomas, and Tabata, 2010). In addition, it should be expected a percentage of missing data caused by: (a) voluntary discharges, (b) inpatients' inability to respond to questionnaires (e.g., intoxicated patients) and (c) inpatients' no participation in all four psychoeducative training sessions. Finally, although we understand the benefits of including follow-up measures to assess long-term effects of the Stop&Go intervention –as previous studies have done (e.g., Duda et al., 2014)– that will not be possible for our program.

The Stop&Go intervention may help patients in early abstinence move towards a healthy and physically active lifestyle and thus, may bring about changes in patients' (1) knowledge acquired, (2) variables related to healthy habits (e.g., exercise motivation) and (3) psychological well-being. In this sense, those patients that autonomously engage in a healthy lifestyle will have tools and resources to prevent future relapses to substance use and to reintegrate into society (Ryan, Lynch, Vansteenkiste, and Deci, 2011).



* Data collected in Study 2 (Phase I) will serve as control group data in Phase II.

Figure 1. Structure of the entire Stop&Go project.

Measure	Patient's admission		Hospitalization Inpatient	Patient's discharge	
	Nursing staff	Inpatient		Nursing staff	Inpatient
Hospitalization					
Sociodemographic data	✓				
Urine toxicology	✓				
Alcohol test	✓				
Carboximeter	✓				✓
Body mass index (BMI)	✓				
Substance use (last 30 days)	✓				
History of substance use	✓				
Detoxification treatment					
Craving for the main substance		✓			✓
Pain		✓			✓
Physical activity and exercise					
International Physical Activity Questionnaires (IPAQ; Booth, 2000)	✓				
Mobility	✓				
Attendance to exercise sessions				✓ (Daily)	
Exercise and walking				✓ (Daily)	
Healthy lifestyle					
Self-care habits	✓				
Nutrition habits	✓				
Percentage of food eaten	✓				
Sleeping time	✓				✓
Healthy lifestyle knowledge*		✓			✓
Psychological**					
Beck Depression Inventory (BDI-II; Beck et al., 1996)		✓			✓
State-Trait Anxiety Inventory (STAI; Spielberger et al., 1983)		✓			✓
Behavioral Regulation in Exercise Questionnaire (BREQ-3; Wilson et al., 2006)		✓			✓
Positive and Negative Affect Scale (PANAS; Watson et al., 1988)		✓			✓
Self-Report on Barriers to Exercising (Niñerola et al., 2006)		✓			✓
Intention to be physically active (Hein et al., 2004)					✓
Stop&Go intervention					
Satisfaction with the intervention					✓

Figure 2. Measures collected in Study 2 (Phase I) and Phase II.

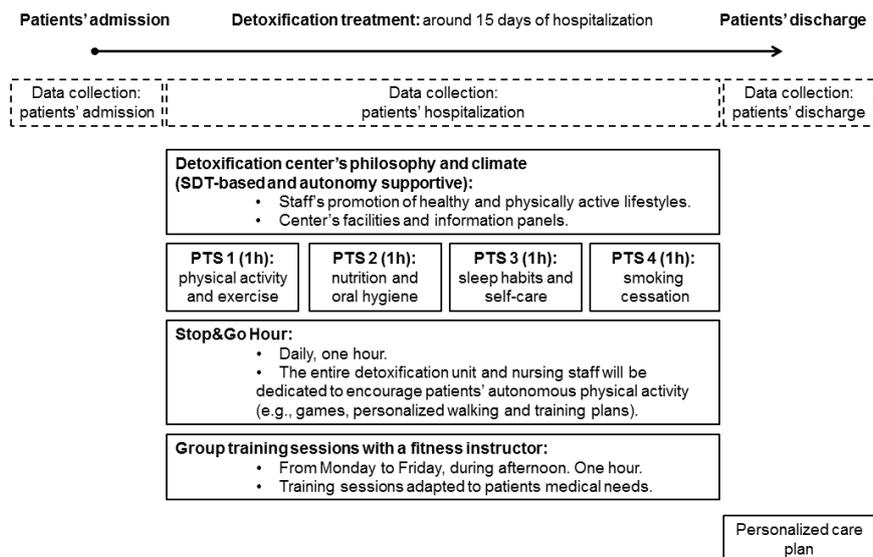


Figure 3. Procedural timeline for Stop&Go intervention and data collection during patients' hospitalization.

PTS = psychoeducational training session.

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PALABRAS CLAVE: Motivación para el ejercicio, adicción a sustancias, vida saludable, actividad física, apoyo a la autonomía, teoría de la autodeterminación.

RESUMEN: El ejercicio puede ayudar a tratar las adicciones a sustancias. Sin embargo, se detecta una falta de programas que promuevan los estilos de vida activa y saludable para pacientes que requieran tratamiento de desintoxicación hospitalaria. Por ello, presentamos el protocolo de un programa de intervención, llamado Stop&Go. Stop&Go incluye dos fases: La Fase I tiene como propósito comprender qué variables se relacionan con la adherencia de estos pacientes a intervenciones que promuevan el estilo de vida saludable. Pacientes con trastornos por uso de sustancias serán invitados a participar en grupos focales (Estudio 1) y a contestar cuestionarios que evalúan variables relacionadas con el ejercicio físico y los hábitos saludables (Estudio 2). La Fase II utilizará el conocimiento obtenido en la Fase I para desarrollar y evaluar una intervención que promueva los hábitos de vida activa y saludable de pacientes ingresados en una unidad hospitalaria de desintoxicación (UHD). Esta intervención se basará también en los postulados de la Teoría de la Autodeterminación. Los pacientes participarán en cuatro sesiones psicoeducativas: (1) actividad física y ejercicio físico, (2) alimentación e higiene bucal, (3) higiene del sueño y autocuidado, y (4) cesación tabáquica. Además, la UHD será adaptada para estimular la práctica autónoma de actividad física, y para reforzar las ideas presentadas en los grupos psicoeducativos. Se espera que, en comparación con el grupo control, los pacientes de la intervención Stop&Go mostrarán: (a) mayores puntuaciones en variables relacionadas con el ejercicio físico, (b) mejor salud mental, y (c) mayor conocimiento sobre los hábitos de vida saludable.

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