

This document is the **Accepted Manuscript version** of a Published Work that appeared in final form in **International Journal of Law and Psychiatry. Vol.74, January–February 2021, 101668**

<https://doi.org/10.1016/j.ijlp.2020.101668>

© 2020. This manuscript version is made available under the CC-BY-NC-ND 4.0 license <https://creativecommons.org/licenses/by-nc-nd/4.0/>

Promoting adherence to psychopharmacological treatment among prisoners with mental health problems: Follow-up of a randomized controlled trial

Alexander Muela, Jone Aliri, Nekane Balluerka, Barbara Presa, Ane Eguren

International Journal of Law and Psychiatry 74 : (2021), 101668

DOI:[10.1016/j.ijlp.2020.101668](https://doi.org/10.1016/j.ijlp.2020.101668)

## **Promoting adherence to psychopharmacological treatment among prisoners with mental health problems: Follow-up of a randomized controlled trial**

AlexanderMuela, JoneAliri, NekaneBalluerka, BarbaraPresa, AneEguren

University of the Basque Country UPV/EHU, Department of Clinical and Health Psychology and Research Methodology, Avenida de Tolosa, 70, 20018 San Sebastián, Gipuzkoa, Spain

Corresponding author.

E-mail addresses: [alexander.muela@ehu.eus](mailto:alexander.muela@ehu.eus) (A. Muela)

### **Abstract**

This study presents follow-up results regarding a treatment adherence programme (TAP) for prisoners, the initial effectiveness of which we previously evaluated in a randomized controlled trial. Here we used an experimental design with two randomized groups and assessment at four time points: baseline (pre-intervention), at 3 months (post-intervention), and at 6 and 9 months after baseline. Participants were 151 prisoners with mental health problems ( $M_{age} = 41.85$ ,  $SD = 10.31$ ) who were randomly assigned to either the TAP or treatment as usual (TAU). Prisoners who completed the TAP showed a greater improvement in treatment adherence at 3 and 9 months, compared with those who received TAU. There were no significant differences between the groups in subjective well-being under medication. The availability of an easy-to-apply, universal programme that is able to promote treatment adherence in the prison context could make a positive contribution to the general health of inmates.

*Keywords:* treatment adherence, prisoners with mental health problems, subjective well-being, randomized controlled trial.

## 1. Introduction

The general health of the prison population is an important public health concern (Baranyi et al., 2019; Fazel & Baillargeon, 2011). Research shows that in comparison with the general population, prison inmates have a higher prevalence of physical and mental health problems (Baranyi et al., 2019; Fazel et al., 2016), including higher rates of illness and disability, sexual health problems, suicide, self-harm, and drug, alcohol and tobacco dependency (European Monitoring Centre for Drugs and Drug Addiction, EMCDDA, 2012; Fazel et al., 2016). Together, these factors have been associated with reduced life expectancy and premature death (Fazel et al., 2016).

Various studies in Spain point to a high prevalence of mental disorders among prison inmates. An important part of this research has been conducted within the framework of the PRECA project, a joint initiative of the Ministry of Health and the General Secretariat for Prisons that over the past decade has gathered epidemiological data about the mental health of inmates in Spanish prisons. In this context, Vicens et al. (2011) studied a total of 707 inmates in five representative prisons housing between 1000 and 1500 prisoners and located in central and eastern Spain. They found that the lifetime prevalence of mental disorders was 84.4%, five times higher than the figure for the general population in Spain (15.7%). In 2016, and also as part of this project, Zabala-Baños et al. (2016) reported an even higher lifetime prevalence (90.2%) of mental disorders in a sample of 184 inmates from three prisons in Madrid. Similar results have been obtained in studies conducted in prisons in southern Spain. For example, López et al. (2016) found a lifetime prevalence of mental disorders of 82.6% among male prisoners interned in two prisons in Andalusia. In the most recent study conducted in Spain, Arnau et al. (2020) likewise found a high presence of mental disorders (around 80%) among 1328 male prisoners referred for penitentiary psychiatric

consultation and followed up over three years in three prisons located in the east of the country.

Data from other European countries suggest that the lifetime prevalence of mental disorders among prisoners is above 75%. For example, a study by Macciò et al. (2015) in Italy found that lifetime psychiatric disorders were present in 88.7% of prisoners. In Germany, Driessen et al. (2006) reported a lifetime prevalence rate of 86.3%. A study by Hassan et al. (2011) in the United Kingdom found that 75% of prisoners presented psychiatric symptoms upon entering custody. Finally, a study of male prisoners in Greece by Fotiadou et al. (2006) found that 78.7% had a mental disorder. A high incidence of mental disorders in the prison population has also been reported in studies carried out in the Americas (Andreoli et al., 2014; James & Glaze, 2006; Simpson et al., 2013), Oceania (Butler et al., 2011; Indig et al., 2016), Africa (Dachew et al., 2015; El-Gilany et al., 2016; Naidoo & Mkize, 2012) and Asia (Assadi et al., 2006; Kugu et al., 2008; Tung et al., 2019).

As regards the type of disorders suffered by prisoners, the review by Fazel et al. (2016) found that the most common psychiatric diagnoses concern the misuse of drugs (prevalence of 30-60% in women and 10-48% in men) and of alcohol (prevalence of 10-24% in women and 18-30% in men). Prevalence rates are also high for major depression (14.1% in women and 10.2% in men) and psychotic illness (3.9% in women and 3.6% in men). These data are in line with those reported in the aforementioned studies in Spain (Arnau et al., 2020; Zabala-Baños et al., 2016; Vicens et al., 2011).

Research has also drawn attention to the high rate of psychiatric comorbidity (Facer-Irwin et al., 2019; Garofalo et al., 2018) which, together with the chronic nature of disorders (Palijan et al., 2010), highlights the complexity of prisoners' mental health problems and the challenge this poses for prison health services. In this context, many

European countries have implemented programmes aimed at the early identification of prisoners with mental health problems so as to offer treatment and promote their recovery while in prison, coupled with referral to specialist community services in order to ensure adequate follow-up and continuity of care upon release.

Treatment of mental disorders in the prison population is primarily pharmacological. In Spain, approximately one in three prisoners is prescribed psychotropic medication (Spanish Government, 2016). Importantly, however, several studies have highlighted that inmates have low rates of adherence to drug treatment (Ehret et al., 2013; Muela et al., 2020; Shelton et al., 2010), as well as low subjective well-being under medication (Muela et al., 2020). This can undermine the overall success of intervention programmes, because as various authors have noted (Ehret et al., 2013; Olver et al., 2011; Shelton et al., 2010), non-compliance with therapeutic prescriptions among prisoners with mental health disorders is associated with greater treatment attrition and increased healthcare costs. In the absence of adequate treatment, these individuals are more likely to relapse, leading to an increase in the number and duration of hospital admissions, heightened severity and treatment resistance, and a rise in completed suicide rates. Research has also found that prisoners with mental health problems are at increased risk of violence and victimization in prison (Fazel et al., 2016). This, combined with the fact that prisoners with mental health problems and poor treatment adherence at the time of their release are at higher risk of suicide during the immediate post-release period (Zlodre & Fazel, 2012), highlights the importance of interventions for promoting adherence to psychopharmacological treatment while in custody.

A number of studies and meta-analyses have also found that poor adherence to psychopharmacological treatment is associated with higher recidivism rates and a

greater use of community health services (Olver et al., 2011; Robertson et al., 2014). However, despite the large numbers of prisoners with mental health disorders who also show poor treatment adherence, very few interventions have been developed to address this problem and improve therapeutic compliance (Muela et al., 2020; Shelton et al., 2010).

In a recent randomized controlled trial, Muela et al. (2020) implemented and evaluated an intervention programme designed to improve adherence to psychopharmacological treatment among prisoners with mental health problems. The programme consists of a brief, transdiagnostic, cognitive-behavioural intervention that also aims to improve subjective well-being under medication (Muela et al., 2020). Here we present follow-up results regarding the effectiveness of this programme. We expected to find that prisoners who participated in the programme would show greater treatment adherence and report better subjective well-being under medication, in comparison with inmates who only received treatment as usual, and that the improvement in treatment adherence would be sustained over time.

## **2. Method**

### *2.1. Participants and design*

The sample comprised 151 male prisoners aged between 21 and 68 years ( $M = 41.85$ ,  $SD = 10.31$ ) who were selected based on the following inclusion criteria: currently serving a prison sentence that would continue for at least one year from the start of the study (thus enabling follow-up); having a mental and/or behavioural disorder; being prescribed psychotropic medication (at the time of the study, 75.64% of participants had been prescribed anxiolytics, 49.37% antidepressants and 34.81% antipsychotics); and no diagnosed intellectual disability. They all had a command of

Spanish sufficient for participation in the programme and for responding to the assessment instruments.

The study involved an experimental design with two randomized groups and assessment at four time points: baseline (pre-intervention), at 3 months (post-intervention), and at 6 and 9 months after baseline.

## 2.2. *Instruments*

The ***Morisky-Green-Levine Medication Adherence Scale*** (MGLS; Spanish adaptation by Val et al., 1992; original scale by Morisky et al., 1986) assesses medication adherence through four questions (Yes/No response) that enquire about treatment compliance. In the Spanish version used here, the questions, which must be asked in a relaxed way in the context of a conversation about the patient's health, are: (1) Do you ever forget to take your medication? (2) Do you take your medication at the appropriate time? (3) When you feel better, do you sometimes stop taking your medication? (4) Sometimes, if you feel worse when you take your medication, do you stop taking it? A highly adherent patient would therefore answer No, Yes, No and No to these four questions and would obtain the maximum score of 4. Around five minutes is needed to apply the scale. In the original validation study Morisky et al. (1986) reported acceptable internal consistency (Cronbach's alpha of .61). The corresponding value in our sample ranged from .47 to .61. Among self-report measures for assessing medication adherence the MGLS is one of the most widely used internationally.

The ***Subjective Well-being under Neuroleptics scale*** (SWN-K; Spanish adaptation by Sanjúan et al., 2012; original scale by Naber et al., 2001) is designed to assess subjective well-being in relation to antipsychotic treatment. The questionnaire has 20 items and uses a 6-point Likert-type scale (from 'Not at all' to 'Very much'). The total score therefore ranges from 20 to 120, and higher scores indicate better subjective well-

being under neuroleptics. Approximately ten minutes are required to administer the scale. The Spanish version of the SWN-K has been shown to have high internal consistency ( $\alpha = .86$ ) and adequate temporal stability over a three-month interval. Internal consistency was also high in the present sample, with values ranging from .75 to .81. In the present study we administered this questionnaire to all participants to assess their subjective perception in relation to psychotropic medication in general, not merely neuroleptics. We believe this is justified given that the items of the SWN-K were developed based on patients' own descriptions of their experience and the instrument has been found to capture not merely satisfaction with antipsychotic treatment but also other aspects such as mental functioning, self-control, emotional regulation, physical functioning and social integration (Sanjúan et al., 2012). Furthermore, a considerable proportion of participants (34.81%) were being treated with neuroleptics.

### 2.3. *Interventions*

**Treatment as usual** (TAU) was receipt of any standard care or treatment in the prison and was available to all study participants, regardless of which group they were randomized to. The only intended difference was that those assigned to the TAU group did not attend the sessions of the treatment adherence programme. Treatment as usual included prescribed medication and access to medical and psychiatric care. In addition, prison healthcare staff gave prisoners individual instructions regarding the correct way of taking their prescribed medication, and responded to any queries or difficulties that arose in this respect. Prisoners also took part in specific group interventions for a variety of risk behaviours, addressing issues such as sexual violence, conflict resolution, and smoking and/or substance use, as indicated.



The *Treatment Adherence Programme for Prisoners with Mental Health Problems*

(TAP; Muela et al., 2020) is a systematic cognitive-behavioural intervention whose main objective is to improve adherence to prescribed medication and promote the psychosocial adjustment of prisoners with mental health problems. The TAP (see Table 1) consists of ten sessions divided into three modules: Introduction to Treatment Adherence (three sessions); Enhancing Treatment Adherence (four sessions); and Preventing Risks to Treatment Adherence (three sessions). Sessions take place weekly and each lasts for 90 minutes. The programme as a whole therefore takes around two and a half months to complete.

**Table 1** Summary of the treatment adherence programme (TAP)

| <b>Module</b>  | <b>Content</b>  |
|--|---|
| <b>Module I</b><br>Introduction to treatment adherence | <ul style="list-style-type: none"><li>• The programme begins by clarifying the concept of mental disorder and debunking various social myths and misinformation that surround mental health problems. It then explores the need for good therapeutic adherence in order to improve health, focusing on ways of promoting adherence and of identifying risk behaviours that may undermine it.</li></ul>  |
| <b>Module II</b><br>Enhancing treatment adherence      | <ul style="list-style-type: none"><li>• This module addresses the way in which adherence to treatment can be strengthened. To this end, erroneous beliefs associated with taking medication are examined, and participants learn about the link between ways of thinking and emotional and behavioural consequences. They are then specifically taught to replace negative beliefs about therapeutic treatment with alternative, more adaptive and more useful thoughts, consistent with an attitude of positive, problem-focused coping. Finally, given that</li></ul> |

|  |   |
|--|---|
|  | <p>people who are being treated for mental health problems often experience greater psychophysiological arousal in response to situations of stress or anxiety, participants learn to control their state of arousal, which is a particularly important skill for strengthening adherence to treatment, preventing relapse and improving the individual's quality of life.</p>  |
| <p><b>Module III</b><br/>Preventing risks to treatment adherence</p> | <ul style="list-style-type: none"> <li>• The final module focuses on strategies for detecting and coping with situations that threaten adherence to treatment. Inmates first receive psychoeducation about how the use of non-prescribed drugs can undermine their treatment adherence and, therefore, their mental health while in prison. The health risks posed by the use of psychoactive drugs outside the therapeutic programme are also addressed. Inmates are then taught skills for identifying unpleasant psychological and/or physiological states that can alert them to the risk of a mental health crisis, and they are provided with a structured action plan to apply in the event that an emotional crisis threatens to lead to a relapse. Finally, time is spent preparing participants to continue applying in everyday life what they have learned during the programme.</li> </ul> |

*Procedure*

Potential participants were identified in a three-stage process. First, the prison healthcare service provided the research team with a list of 275 prisoners who had been prescribed psychotropic medication for mental health problems. Their mental health status had been assessed in accordance with the criteria of the International

Classification of Diseases 10th revision (ICD-10) by psychiatrists attached to the prison's healthcare service, who were also responsible for prescribing medication.

Second, we eliminated from the list all those prisoners who had less than one year of their sentence still to serve. Finally, the 260 inmates who met all the inclusion criteria were invited to take part in the study. Of these, 192 agreed to participate and signed informed consent.

The selected participants were then randomly assigned to one of two groups: experimental (the group who would receive the TAP) and control (those who would only receive TAU). Group assignment was based on a 1:1 allocation ratio, such that 96 participants were randomly assigned to each group. The computer-generated random number list was created by a researcher with no clinical involvement in the intervention.

Next, we collected sociodemographic data from all participants and took baseline measures of treatment adherence and subjective well-being under medication using the two instruments described above. The TAP was then administered according to the established protocol (for details, see the supplementary file in Muela et al., 2020). Both treatment adherence and subjective well-being under medication were subsequently re-assessed at 3, 6 and 9 months from the start of the intervention. Of the 192 randomly assigned participants, 7 prisoners in the TAP group did not complete the intervention. In addition, 13 inmates in the TAP group and 21 in the TAU group were lost to follow-up at 3 months, the main reasons being transfer to another prison, interruption of treatment (relapse) and not wishing to continue in the study. The final sample for analysis therefore comprised 151 individuals (75 in the TAU group and 76 in the TAP group).

It should be noted that it was made clear to inmates that they would receive no sentence- or prison-related benefits for participating in the study or as a result of their

assessment responses. Indeed, they were informed that their responses would not be shared with the prison authorities and that the sole purpose of the assessments was to evaluate the effectiveness of the programme. All the assessments were carried out by a clinical psychologist who was blind to the treatment condition. Assessments were conducted individually with each inmate and within the prison.

The study was conducted in a prison in Álava, Spain. Opened in 2011, the prison building occupies 87,658 square metres (m<sup>2</sup>) on a total land area of 438,571 m<sup>2</sup>. It has four storeys and 720 cells of 13 m<sup>2</sup>, plus a further 304 complementary cells. The main cells are designed to house two prisoners, and thus the total prison population may reach 1,440 (for further details, see Muela et al., 2020). This prison is classified as an ordinary regime for second-grade prisoners, and it was chosen for three main reasons: the interest shown by its governing board in implementing a treatment adherence programme, the possibility of recruiting a large number of participants, and the fact that it is run in a way that is representative of the majority of Spanish prisons. The study was approved by the Spanish government's General Secretariat for Prisons, as well as by the Research Ethics Committee of the University of the Basque Country (northern Spain).

### **3. Data analysis**

In order to examine whether participation in the TAP led to a sustained increase in adherence to drug treatment and subjective well-being under medication among prisoners with mental health problems, and to analyse whether this increase was similar to that achieved with TAU, we used a linear mixed model, which assumes that the measurements of each experimental unit are correlated. Specifically, and due to the longitudinal nature of the data, we used the first-order autoregressive covariance structure. As the interaction between the treatment factor and the time factor was

statistically significant, we performed simple effects analysis with Bonferroni correction to examine whether the two treatment conditions had different effects on treatment adherence at each of the follow-up points. All data analyses were performed using SPSS 26.0.

## 4. Results

### 4.1. Descriptive analysis

Table 2 shows the baseline characteristics of the sample according to treatment condition.

**Table 2**

*Sample characteristics by treatment condition*

|                                   | Treatment as usual<br>(TAU)<br>( <i>n</i> = 75) | Treatment adherence<br>programme (TAP)<br>( <i>n</i> = 76) |
|-----------------------------------|---|--|
| <b>Sociodemographic variables</b> |   |  |
| Age in years, mean (SD)           | 43.14 (10.22)                                   | 40.61 (10.31)  |
| Country of origin, <i>n</i> (%)   |   |  |
| Spain                             | 64 (85.3)                                       | 64 (84.2)  |
| Colombia                          | 3 (4.0)   | 5 (6.6)  |
| Morocco                           | 3 (4.0)   | 3 (3.9)  |
| Dominican Republic                | 2 (2.7)   | 0  |
| Portugal                          | 1 (1.3)   | 0  |
| France                            | 0   | 1 (1.3)  |
| Argentina                         | 1 (1.3)   | 0  |

|  |               |                |
|--|---------------|----------------|
| Bolivia  | 1 (1.3)       | 0              |
| Uruguay  | 0             | 1 (1.3)        |
| Algeria  | 0             | 1 (1.3)        |
| Senegal  | 0             | 1 (1.3)        |
| Educational level, <i>n</i> (%)                      |               |                |
| No formal qualifications                             | 39 (52)       | 35 (46.1)      |
| Secondary/intermediate-level vocational training     | 34 (45.3)     | 40 (52.6)      |
| University/higher-level vocational training          | 2 (2.7)       | 1 (1.3)        |
| Months of sentence remaining, mean (SD)              | 87.93 (82.29) | 100.53 (85.42) |
| Type of crime for which convicted, <i>n</i> (%)      |               |                |
| Offences against property and economic interests     | 30 (40.0)     | 30 (39.47)     |
| Homicide and its forms                               | 15 (20.0)     | 23 (30.26)     |
| Other  | 30 (40.0)     | 23 (30.26)     |
| Mental and behavioural disorders, <i>n</i> (%)       |               |                |
| Related to substance use                             | 26 (34.7)     | 33 (43.4)      |
| Schizophrenia spectrum and other psychotic disorders | 3 (4.0)       | 4 (5.3)        |
| Personality disorder                                 | 2 (2.7)       | 1 (1.3)        |
| Not categorized but with anxiety/depressive symptoms | 44 (58.7)     | 38 (50.0)      |

|   |               |               |
|---|---------------|---------------|
| Adherence to drug treatment, mean<br>(SD)               | 2.92 (1.14)   | 2.79 (1.19)   |
| Subjective well-being under<br>medication,<br>mean (SD) | 94.95 (13.83) | 88.80 (13.22) |

There were no differences between the TAU and TAP groups on any of the sociodemographic variables. However, the groups did differ significantly in subjective well-being under medication ( $t(149) = 2.791, p = .006, d = 0.45$ ). Consequently, the baseline score on this variable was entered as a covariate in the linear mixed model that analysed subjective well-being under medication in relation to treatment condition and assessment point.

#### 4.2. Main statistical analyses

The results from the linear mixed model with treatment adherence as the dependent variable indicated that both the treatment condition ( $F(1, 164.8) = 7.35; p = .007$ ) and the assessment point ( $F(3, 307.4) = 20.58; p < .001$ ) were statistically significant. The interaction between these two factors was also significant ( $F(3, 307.4) = 5.13; p = .002$ ). We therefore analysed the simple effects, that is, the difference between the two treatments at each time point. With respect to the linear mixed model analysing subjective well-being under medication, the results showed, after controlling for the between-group differences observed at baseline, that neither the treatment condition nor the assessment point nor the interaction between the two was statistically significant. The results of these analyses are shown in Table 3. Specifically, the table shows the estimated means (and 95% confidence interval) for treatment adherence and subjective well-being

under medication for each treatment condition at each measurement point, as well as the difference in means between groups and the level of significance.

**Table 3**

*Estimated means [95% CI], difference in means between the TAU and TAP groups and level of significance (p)*

|   | TAU (n = 75)     | TAP (n = 76)     | Diff.<br>TAU-TAP | p    |
|---|------------------|------------------|------------------|------|
| <b>Treatment adherence</b>                    |                  |                  |                  |      |
| Baseline                                      | 2.9 [2.7-3.1]    | 2.8 [2.6-3.0]    | 0.13             | .414 |
| 3 months                                      | 3.2 [3.0-3.4]    | 3.7 [3.5-3.9]    | -0.50            | .002 |
| 6 months                                      | 3.3 [3.0-3.5]    | 3.6 [3.3-3.8]    | -0.30            | .093 |
| 9 months                                      | 3.3 [3.0-3.6]    | 3.9 [3.6-4.2]    | -0.60            | .004 |
| <b>Subjective well-being under medication</b> |                  |                  |                  |      |
| Baseline                                      |                  |                  |                  |      |
| 3 months                                      | 94.1 [91.8-96.4] | 96.9 [94.6-99.1] | -2.75            | .098 |
| 6 months                                      | 94.0 [91.4-96.6] | 96.9 [93.9-99.9] | -2.88            | .155 |
| 9 months                                      | 96.8 [93.8-99.2] | 95.9 [92.7-99.1] | 0.91             | .690 |

It can be seen in the table that the mean score on treatment adherence was significantly higher among prisoners who received the TAP, compared with those in the TAU groups, at both 3 months ( $p = .002$ ) and 9 months ( $p = .004$ ). Although the TAP group also scored higher at the 6-month follow up, the difference was not statistically significant.

## 5. Discussion



The main aim of this randomized controlled study was to examine the effectiveness of an intervention designed to promote adherence to psychopharmacological treatment among prisoners with mental health problems. Outcomes among prisoners who took part in the treatment adherence programme (TAP) were compared both at the end of the intervention and up to six months later with those of a group of inmates in the same prison who only received standard treatment (TAU). We also examined whether the TAP had an impact on prisoners' subjective well-being under medication.

Participation in the TAP was associated with an increase in the rate of treatment adherence, and this increase was sustained over time. Given that psychopharmacological treatment is the first-line approach to managing psychiatric disorders in the prison population, these results reinforce the need for and potential benefits of specific interventions to promote treatment adherence. As noted by the World Health Organization (2003), strategies that are able to increase treatment adherence may play a key role in closing the gap between the expected and actual effectiveness of clinical interventions, thereby helping to improve the overall efficiency of health systems. It has also been suggested that increasing the effectiveness of adherence interventions may have a greater impact on people's health than would any improvement in specific medical treatments (WHO, 2003). This is especially important in the prison context, since various studies have associated low treatment adherence with negative health consequences for prisoners, both during incarceration (increased rate of relapse, of violent incidents and homicides, etc.) and following release (increased risk of suicide and of recidivism, and greater reliance on community health services) (Fazel et al., 2016; Olver et al., 2011; Robertson et al., 2014; Zlodre & Fazel, 2012).

In the present study, prisoners who received the TAP showed a greater improvement in treatment adherence at the end of the follow-up period, as compared with inmates in the TAU group. From a conceptual point of view, both the TAP and the standard treatment that is offered in the prison where the study was conducted include components that promote adherence to psychopharmacological treatment, for example, providing a personalized explanation of the prescribed treatment (Bressington et al., 2008), listening to patients' concerns (Bowen et al., 2009), promoting an internal locus of control (Bentley & Casey, 2017) and avoiding the use of coercive strategies to make patients take their medication (Dlugacz & Wimmer, 2013; Farabee et al., 2004). However, the TAP goes further in that it is a structured, cognitive-behavioural programme that aims to teach participants skills for coping with stress and crisis situations while in custody, for example, events that increase their risk of a psychological breakdown (arguments, fights, receiving bad news, etc.) or their transfer from one prison to another.

It should also be noted that, among psychotherapeutic approaches, various studies and reviews have found that cognitive-behavioural therapy is effective in reducing clinical symptoms and preventing relapses among prisoners with psychiatric disorders (Fazel et al., 2016; Jalali et al., 2019; Kouyoumdjian et al., 2015). Our results here support this view, insofar as the TAP, a cognitive-behavioural intervention, had a greater impact on treatment adherence than did TAU, which primarily involved medical and psychiatric supervision. In our opinion, the recommendation to use cognitive-behavioural strategies should be extended by specifying that the intervention should also be transdiagnostic.

Regarding subjective well-being under medication, both the TAP and TAU led to improvement in this variable, and the results showed no differences between the two interventions in this respect. There are a number of possible explanations for this.

First, as we noted in the introduction, there is a high prevalence of mental health problems among prisoners, although few of them follow adequate psychiatric treatment while in prison (Muela et al., 2020). Our findings here suggest that merely receiving some degree of medical advice and supervision can help to improve subjective well-being under medication. The fact that we observed no differences between the TAP and TAU groups in this regard highlights the limitations of the programme to influence this variable, although this may be because it is focused primarily on treatment adherence and the management of crisis situations.

Our result may also suggest that subjective well-being under psychotropic medication depends less on adherence per se and more on whether or not the medication in question also produces adverse effects. Various studies have shown that psychotropic drugs can produce important side effects such as extrapyramidal reactions and metabolic changes (Hervás et al., 2019; Serretti et al., 2013). Thus, if interventions aimed at improving treatment adherence among prisoners also wish to improve subjective well-being under medication, they need to include psychoeducational components, such as detailed explanation of the prescribed treatment, advice on adapting to a new dose, explaining the effects of non-compliance, identifying the warning signs of a psychological crisis, promoting an internal locus of control, challenging the idea that medication is simply a form of control, and helping the individual to see the benefits (both primary and secondary) of taking medication. It is also essential to pay attention to the patient's concerns. In this respect, and given the high rate of antipsychotic prescription in the prison context (Hervás et al., 2019), it

should be remembered than more than one such drug is often used concomitantly in treating mental disorders, even though this is not recommended in clinical guidelines (Hervás et al., 2019). Given that antipsychotic polytherapy has been linked to a greater number of side effects and pharmacokinetic interactions, we support the recommendation to encourage monotherapy (Hervás et al., 2019), since any strategy that helps to reduce the adverse effects of taking medication is likely to improve the person's subjective well-being under pharmacological treatment. Obviously, these possible explanations for the results we obtained would need to be tested in further studies.

## **6. Limitations and conclusions**

This study has a number of limitations. First, the fact that the two groups differed in how much of their sentence remained to be served is potentially a factor that could have influenced the results. Second, the study was carried out in a single prison, and it would therefore be useful to recruit participants from across different institutions to examine how the TAP performs in other settings. Another issue is that all the participants were male. It is worth noting in this respect that the number of women in prison is growing considerably, and research has shown that, as in the case of men, the prevalence of mental health problems and prescribed psychotropic medication is high among females (Bentley & Casey, 2017). Future studies should therefore examine the impact of the TAP in a sample of female prisoners. It would also be useful to adapt and evaluate the effectiveness of the programme in persons who present intellectual disability in addition to mental health problems. More studies are likewise needed to study its impact among foreign nationals who are incarcerated in Spanish prisons. Although they only accounted for 15.2% of the present sample, foreign nationals currently make up 28% of the prison

population in Spain (General Secretariat for Prisons, 2019). It would also be interesting to explore in a longitudinal study whether the effect of the TAP differs according to the type of psychological or psychiatric disorder, although this would require a larger number of participants, since as we have seen here, sample attrition is an important problem. A larger sample is also needed to examine the extent to which our results are generalizable to the Spanish prison population as a whole.

Another issue of concern in the prison context is the high rate of suicide among inmates with mental health problems, which is often associated with traumatic life events (Fazel et al., 2016; Sánchez et al., 2018). Several studies have found a close relationship between suicidal behaviour and non-adherence to treatment (Higashi et al., 2013; Jawad et al., 2018). Given the known association between psychopathology and suicide risk among prison inmates (Saavedra & López, 2015), it would therefore be interesting to evaluate the impact of the TAP among prisoners who present mental health problems, risk factors for suicide (ideation, previous attempts, etc.) and poor treatment adherence.

To conclude, in addition to providing empirical evidence for the effectiveness of the TAP, the results of this study provide a scientific basis for recommending the use of psychological interventions to improve adherence to psychopharmacological treatment in the prison environment. Given the high prevalence of psychiatric disorders among prisoners, and the fact that psychotropic medication is the primary treatment, the availability of an easy-to-apply, universal programme that is able to improve treatment adherence could make a positive contribution to the general health of inmates. The TAP may also help to achieve better post-release outcomes and reduce reliance on community health services, since high adherence is one of the factors that prevent recidivism.

## **Acknowledgements**

This research was funded by a grant from the Basque Government (IT892-16) and by a grant from Otsuka Pharmaceutical, S.A.

## 7. References

- Andreoli, S. B., dos Santos, M. M., Quintana, M. I., Ribeiro, W. S., Blay, S. L., Taborda, J. G. V., & de Jesus Mari, J. (2014). Prevalence of mental disorders among prisoners in the state of Sao Paulo, Brazil. *PLoS One*, *9*(2), e88836. <http://dx.doi.org/10.1371/journal.pone.0088836>
- Arnau, F., García-Guerrero, J., Benito, A., Vera-Remartínez, E. J., Baquero, A., & Haro, G. (2020). Sociodemographic, clinical, and therapeutic aspects of penitentiary psychiatric consultation: Toward integration into the general mental health services. *Journal of Forensic Sciences*, *65*(1), 160-165. <http://dx.doi.org/10.1111/1556-4029.14137>
- Assadi, S. M., Noroozian, M., Pakravannejad, M., Yahyazadeh, O., Aghayan, S., Shariat, S. V., & Fazel, S. (2006). Psychiatric morbidity among sentenced prisoners: prevalence study in Iran. *The British Journal of Psychiatry*, *188*(2), 159-164. <http://dx.doi.org/10.1192/bjp.188.2.159>
- Baranyi, G., Scholl, C., Fazel, S., Patel, V., Priebe, S., & Mundt, A. P. (2019). Severe mental illness and substance use disorders in prisoners in low-income and middle-income countries: A systematic review and meta-analysis of prevalence studies. *The Lancet Global Health*, *7*(4), e461-e471. [https://doi.org/10.1016/S2214-109X\(18\)30539-4](https://doi.org/10.1016/S2214-109X(18)30539-4)

- Bentley, K. J., & Casey, R. C. (2017). Incarcerated women's experiences and beliefs about psychotropic medication: An empirical study. *Psychiatric Services, 68*(4), 384-389. <https://doi.org/10.1176/appi.ps.201600078>
- Bowen, R. A., Rogers, A., & Shaw, J. (2009). Medication management and practices in prison for people with mental health problems: a qualitative study. *International Journal of Mental Health Systems, 3*(1), 24. <https://doi.org/10.1186/1752-4458-3-24>
- Bressington, D., Gray, R., Lathlean, J., & Mills, A. (2008). Antipsychotic medication in prisons: satisfaction with and adherence to treatment. *Mental Health Practice, 11*(10) 18-21. <http://dx.doi.org/10.7748/mhp2008.07.11.10.18.c6612>
- Butler, T., Indig, D., Allnutt, S., & Mamoon, H. (2011). Co-occurring mental illness and substance use disorder among Australian prisoners. *Drug and Alcohol Review, 30*(2), 188-194. <http://dx.doi.org/10.1111/j.1465-3362.2010.00216.x>
- Dachew, B. A., Fekadu, A., Kisi, T., Yigzaw, N., & Bisetegn, T. A. (2015). Psychological distress and associated factors among prisoners in North West Ethiopia: cross-sectional study. *International Journal of Mental Health Systems, 9*(1), 39. <http://dx.doi.org/10.1186/s13033-015-0033-7>
- Dlugacz, H., & Wimmer, C. (2013). Legal aspects of administrating antipsychotic medications to jail and prison inmates. *International Journal of Law and Psychiatry, 36*(3-4), 213-228. <https://doi.org/10.1016/j.ijlp.2013.04.001>
- Driessen, M., Schroeder, T., Widmann, B., von Schonfeld, C., & Schneider, F. (2006). Childhood trauma, psychiatric disorders, and criminal behavior in prisoners in Germany: A comparative study in incarcerated women and men. *Journal of Clinical Psychiatry, 67*(10), 1486-1492. <https://doi.org/10.4088/JCP.v67n1001>

- Ehret, M. J., Shelton, D., Barta, W., Trestman, R., Maruca, A., Kamath, J., & Golay, L. (2013). Medication adherence among female inmates with bipolar disorder: Results from a randomized controlled trial. *Psychological Services, 10*(1), 106-114. <https://doi.org/10.1037/a0031433>
- El-Gilany, A., Khater, M., Gomaa, Z., Hussein, E., & Hamdy, I. (2016). Psychiatric disorders among prisoners: a national study in Egypt. *East Asian Archives of Psychiatry, 26*(1), 30-38.
- European Monitoring Centre for Drugs and Drug Addiction, EMCDDA (2012). *Prisons and drugs in Europe: The problem and responses*. EMCDDA. Retrieved from: [http://www.emcdda.europa.eu/system/files/publications/747/TDSII2002ENC\\_3\\_99981.pdf](http://www.emcdda.europa.eu/system/files/publications/747/TDSII2002ENC_3_99981.pdf)
- Facer-Irwin, E., Blackwood, N. J., Bird, A., Dickson, H., McGlade, D., Alves-Costa, F., & MacManus, D. (2019). PTSD in prison settings: A systematic review and meta-analysis of comorbid mental disorders and problematic behaviours. *PLoS One, 14*(9). <http://dx.doi.org/10.1371/journal.pone.0222407>
- Farabee, D., Shen, H., & Sanchez, S. (2004). Program-level predictors of antipsychotic medication adherence among parolees. *International Journal of Offender Therapy and Comparative Criminology, 48*(5), 561-571. <https://doi.org/10.1177/0306624X04263884>
- Fazel, S., & Baillargeon, J. (2011). The health of prisoners. *The Lancet, 377*(9769), 956-965. [https://doi.org/10.1016/S0140-6736\(10\)61053-7](https://doi.org/10.1016/S0140-6736(10)61053-7)
- Fazel, S., Hayes, A. J., Bartellas, K., Clerici, M., & Trestman, R. (2016). Mental health of prisoners: Prevalence, adverse outcomes, and interventions. *The Lancet Psychiatry, 3*(9), 871–881. [http://dx.doi.org/10.1016/S2215-0366\(16\)30142-0](http://dx.doi.org/10.1016/S2215-0366(16)30142-0)



- Fotiadou, M., Livaditis, M., Manou, I., Kaniotou, E., & Xenitidis, K. (2006). Prevalence of mental disorders and deliberate self-harm in Greek male prisoners. *International Journal of Law and Psychiatry*, 29(1), 68-73. <https://doi.org/10.1016/j.ijlp.2004.06.009>
- Garofalo, C., Velotti, P., Crocamo, C., & Carrà, G. (2018). Single and multiple clinical syndromes in incarcerated offenders: Associations with dissociative experiences and emotionality. *International Journal of Offender Therapy and Comparative Criminology*, 62(5), 1300-1316. <https://doi.org/10.1177/0306624X16682325>
- General Secretariat for Prisons. (2019). *Penitentiary statistics*. Madrid (Spain) SGIP. Retrieved from <https://www.institucionpenitenciaria.es/es/webweb/portal/documentos/instrucciones/index.html>
- Hassan, L., Birmingham, L., Harty, M. A., Jarrett, M., Jones, P., King, C., ... & Thornicroft, G. (2011). Prospective cohort study of mental health during imprisonment. *The British Journal of Psychiatry*, 198(1), 37-42. <https://doi.org/10.1192/bjp.bp.110.080333>
- Higashi, K., Medic, G., Littlewood, K. J., Diez, T., Granström, O., & De Hert, M. (2013). Medication adherence in schizophrenia: factors influencing adherence and consequences of nonadherence, a systematic literature review. *Therapeutic Advances in Psychopharmacology*, 3(4), 200-218. <http://dx.doi.org/10.1177/2045125312474019>
- Hervás, G., Ruano, C., Sanz-Alfayate, G., Algora, I., Celdran, M. A., & Mur, M. A. (2019). Análisis del manejo de antipsicóticos inyectables de larga duración en varios centros penitenciarios [Analysis of the management of long-acting injectable antipsychotics in a group of prisons]. *Revista Española de Sanidad*

*Penitenciaria*, 21(2), 88-94. <http://dx.doi.org/10.4321/S1575-06202019000200004>

Indig, D. (2016). *Comorbid substance use disorders and mental health disorders among New Zealand prisoners*. Wellington: New Zealand Department of Corrections.

Jalali, F., Hasani, A., Hashemi, S. F., Kimiaei, S. A., & Babaei, A. (2019). Cognitive group therapy based on schema-focused approach for reducing depression in prisoners living with HIV. *International Journal of Offender Therapy and Comparative Criminology*, 63(2), 276-288. <https://doi.org/10.1177/0306624X18784185>

James, D. J., & Glaze, L. E. (2006). *Mental health problems of prison and jail inmates*. Washington, DC: US Department of Justice, Bureau of Justice Statistics.

Jawad, I., Watson, S., Haddad, P. M., Talbot, P. S., & McAllister-Williams, R. H. (2018). Medication nonadherence in bipolar disorder: a narrative review. *Therapeutic Advances in Psychopharmacology*, 8(12), 349-363. <http://dx.doi.org/10.1177/2045125318804364>

Kouyoumdjian, F. G., McIsaac, K. E., Liauw, J., Green, S., Karachiwalla, F., Siu, W., ... & Korchinski, M. (2015). A systematic review of randomized controlled trials of interventions to improve the health of persons during imprisonment and in the year after release. *American Journal of Public Health*, 105(4), e13-e33. <https://doi.org/10.2105/AJPH.2014.302498>

Kugu, N. E. S. İ. M., Akyuz, G., & Dogan, O. (2008). Psychiatric morbidity in murder and attempted murder crime convicts: A Turkey study. *Forensic Science International*, 175(2-3), 107-112. <http://dx.doi.org/10.1016/j.forsciint.2007.05.016>

- López, M., Saavedra, F. J., López, A., & Laviana, M. (2016). Prevalence of mental health problems in sentenced men in prisons from Andalusia (Spain). *Revista Española de Sanidad Penitenciaria*, 18(3), 76-84.
- Macciò, A., Meloni, F. R., Sisti, D., Rocchi, M. B. L., Petretto, D. R., Masala, C., & Preti, A. (2015). Mental disorders in Italian prisoners: Results of the REDiMe study. *Psychiatry Research*, 225(3), 522-530.  
<https://doi.org/10.1016/j.psychres.2014.11.053>
- Morisky D. E., Green L. W., & Levine D. M. (1986). Concurrent and predictive validity of a self-reported measure of medication adherence. *Medical Care*, 24, 67-74.  
<https://doi.org/10.1097/00005650-198601000-00007>
- Muela, A., Aliri, J., Presa, B., & Gorostiaga, A. (2020). Randomised controlled trial of a treatment adherence programme for prisoners with mental health problems in Spain. *Criminal Behaviour and Mental Health*, 30(1), 6-15.  
<https://doi.org/10.1002/cbm.2142>
- Naber, D., Moritz, S., Lambert, M., Rajonk, F., Holzbach, R., Mass, R., ... & Burghard, A. (2001). Improvement of schizophrenic patients' subjective well-being under atypical antipsychotic drugs. *Schizophrenia Research*, 50(1), 79-88.  
[https://doi.org/10.1016/S0920-9964\(00\)00166-3](https://doi.org/10.1016/S0920-9964(00)00166-3)
- Naidoo, S., & Mkize, D. L. (2012). Prevalence of mental disorders in a prison population in Durban, South Africa. *African Journal of Psychiatry*, 15(1), 30-35.
- Olver, M. E., Stockdale, K. C., & Wormith, J. S. (2011). A meta-analysis of predictors of offender treatment attrition and its relationship to recidivism. *Journal of Consulting and Clinical Psychology*, 79(1), 6-21.  
<https://doi.org/10.1037/a0022200>

- Palijan, T., Radeljak, S., Kovač, M., & Kovačević, D. (2010). Relationship between comorbidity and violence risk assessment in forensic psychiatry: The implication of neuroimaging studies. *Psychiatria Danubina*, 22(2), 253-256.
- Robertson, A. G., Swanson, J. W., Van Dorn, R. A., & Swartz, M. S. (2014). Economic grand rounds: treatment participation and medication adherence: effects on criminal justice costs of persons with mental illness. *Psychiatric Services*, 65(10), 1189-1191. <http://dx.doi.org/10.1176/appi.ps.201400247>
- Saavedra, J., & López, M. (2015). Risk of suicide in male prison inmates. *Revista de Psiquiatría y Salud Mental*, 8(4), 224-231. <http://dx.doi.org/10.1016/j.rpsmen.2013.07.002>
- Sánchez, F. C., Fearn, N., & Vaughn, M. G. (2018). Risk factors associated with near-lethal suicide attempts during incarceration among men in the Spanish prison system. *International Journal of Offender Therapy and Comparative Criminology*, 62(6), 1452-1473. <https://doi.org/10.1177/0306624X16689833>
- Sanjúan, J., Haro, J. M., Mauriño, J., Díez, T., & Ballesteros, J. (2012). Validación de la versión en castellano de la Escala del Bienestar Subjetivo con Neurolépticos (SWN-K) en pacientes con esquizofrenia [Validation of the Spanish version of the Subjective Well-being under Neuroleptics scale]. *Medicina Clínica*, 138(4), 151-154. <https://doi.org/10.1016/j.medcli.2011.02.031>
- Serretti, A., Chiesa, A., Calati, R., Fabbri, C., Sentissi, O., De Ronchi, D., ... & Souery, D. (2013). Side effects associated with psychotropic medications in patients with bipolar disorder: evidence from two independent samples. *Journal of Psychopharmacology*, 27(7), 616-628. <http://dx.doi.org/10.1177/0269881113485143>

- Simpson, A. I., McMaster, J. J., & Cohen, S. N. (2013). Challenges for Canada in meeting the needs of persons with serious mental illness in prison. *Journal of the American Academy of Psychiatry and the Law Online*, 41(4), 501-509.
- Shelton, D., Ehret, J., Wakai, S., Kapetanovic, T., & Moran, M. (2010). Psychotropic medication adherence in correctional facilities: A review of the literature. *Journal of Psychiatric and Mental Health Nursing*, 17, 603–613. <https://doi.org/10.1111/j.1365-2850.2010.01587.x>
- Spanish Government. (2016). Encuesta sobre salud y consumo de drogas en instituciones penitenciarias [Survey on health and drug use in prisons]. Madrid (Spain). Retrieved from <https://pnsd.sanidad.gob.es/profesionales/sistemasInformacion/sistemaInformacion/pdf/2016ESDIP.pdf>
- General Secretariat for Prisons. (2019). *Penitentiary statistics*. Madrid (Spain) SGIP. Retrieved from <https://www.institucionpenitenciaria.es/es/webweb/portal/documentos/instrucciones/index.html>
- Tung, T. H., Hsiao, Y. Y., Shen, S. A., & Huang, C. (2019). The prevalence of mental disorders in Taiwanese prisons: a nationwide population-based study. *Social Psychiatry and Psychiatric Epidemiology*, 54(3), 379-386.
- Val, A. J., Amorós, G. B., Martínez, P. V., Fernández, M. F., & León, M. S. (1992). Descriptive study of patient compliance in pharmacologic antihypertensive treatment and validation of the Morisky and Green test. *Atención Primaria*, 10(5), 767-770. <http://dx.doi.org/10.1007/s00127-018-1614-y>
- Vicens, E., Tort, V., Dueñas, R.M., Muro, A., Pérez, F., Arroyo, J.M., Acín, E., De Vicente, A., Guerrero, R., Lluch, J., Planella, R., & Sarda, P. (2011). The

prevalence of mental disorders in Spanish prisons. *Criminal Behavior and Mental Health*, 21, 321-332. <https://doi.org/10.1002/cbm.815>

World Health Organization. (2003). *Adherence to long-term therapies: Evidence for action*. World Health Organization.

Zabala-Baños, M. C., Segura, A., Maestre-Miquel, C., Martínez-Lorca, M., Rodríguez-Martín, B., Romero, D., & Rodríguez, M. (2016). Mental disorder prevalence and associated risk factors in three prisons of Spain. *Revista Española de Sanidad Penitenciaria*, 18(1), 13-23. <http://dx.doi.org/10.4321/S1575-06202016000100003>

Zlodre, J., & Fazel, S. (2012). All-cause and external mortality in released prisoners: Systematic review and meta-analysis. *American Journal of Public Health*, 102(12), e67-e75. <https://doi.org/10.2105/AJPH.2012.300764>