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# Impact of the Unified Protocol on Attenuated Psychotic Symptoms, Cognitive Biases and Cognitive Insight in Patients at Ultra High Risk (UHR) for Psychosis: Secondary Results of a Pilot Randomized Controlled Trial

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## ABSTRACT

**Background and Hypothesis:** Ultra high risk (UHR) for psychosis can have different clinical trajectories but the remission rates are only 51.9% after 3 years of follow-up. Deficits in metacognition are associated with severity of symptoms and poor response to treatment. We hypothesize that the Unified Protocol for the Transdiagnostic Treatment of Emotional Disorders (UP) will have a positive effect on attenuated psychotic symptoms, cognitive biases and cognitive insight in UHR individuals.

**Study Design:** This article reports the secondary analyses of a pilot randomized controlled trial with 36 UHR participants assigned to either an online group intervention with UP plus Treatment as Usual (UP + TAU) or TAU alone. Assessments were conducted at baseline, post-intervention and 3-month follow-up and included the severity and distress of attenuated psychotic symptoms (CAARMS), cognitive biases (CBQp) and cognitive insight (BCIS).

**Study Results:** Significant differences were found in the evolution of the two groups in CAARMS distress scores in favor of the UP condition group. Significant differences in CBQp scores between the two groups were found in the two time assessments in favor of the UP group. No significant differences were found in cognitive insight.

**Conclusions:** The UP intervention showed promising effects in reducing distress related to attenuated psychotic symptoms and cognitive biases, but not in improving cognitive insight. Given the small sample size, which fell below the initial target, and the pilot nature of the study, these findings should be interpreted with caution and considered preliminary until replicated in adequately powered trials.

Susana Ochoa and Jorge Osma contributed equally as senior authors.

## 1 | Introduction

The concept of ultra-high risk for psychosis (UHR) was developed to improve early detection and intervention in psychotic patients and thereby improve prognosis (Yung et al. 2005). Research has shown that UHR patients can experience various clinical trajectories beyond the transition to psychosis, such as relapses or the recurrence of attenuated psychotic symptoms (Polari et al. 2018) (which differ in intensity, frequency and/or duration from overt psychotic symptoms) (Yung et al. 2005), with the frequency of remission of attenuated psychotic symptoms being only 51.9% (Salazar de Pablo et al. 2022). Improved early intervention is therefore crucial to reduce the risk of poor outcomes. This is supported by some studies that conclude that remission rates are still low after various active interventions (Simon et al. 2013). Emotional comorbidities, particularly anxiety and depressive disorders, are highly prevalent among individuals at ultra-high risk for psychosis (Fusar-Poli et al. 2014; Rutigliano et al. 2016; Solmi et al. 2023) and are associated with poorer outcomes and greater distress (Fusar-Poli et al. 2020; Rutigliano et al. 2016).

As important components of metacognition (Moritz and Lysaker 2018), cognitive biases play a central role in the development of delusions in early psychosis (van der Gaag et al. 2012; van der Gaag et al. 2013). The most widespread cognitive biases are intentionalization, catastrophizing, dichotomous thinking, jumping to conclusions (JTC), and emotion-based reasoning, and these may already be observed in the UHR phase (Gawęda et al. 2024; van der Gaag et al. 2013). Cognitive biases also correlate with greater symptom severity and poorer cognitive insight in patients with psychosis (Corral et al. 2020). JTC bias (Dudley et al. 2015; Garety et al. 2011) is specifically associated with the development and persistence of delusions, deficits in social information processing, neuropsychological impairment, and increased involuntary psychiatric admissions in patients with a first episode of psychosis (Díaz-Cutraro et al. 2021; Díaz-Cutraro et al. 2022; Dudley et al. 2015). In addition, patients with low cognitive flexibility and JTC bias generally respond poorly to treatment (Garety et al. 2015). Despite these findings, research on cognitive distortions other than JTC in UHR patients is limited to date (Gawęda et al. 2024).

Metacognition also includes cognitive insight, that is, the ability to understand and reflect on one's own mental states and those of others (Beck 2004). This includes self-reflectiveness (SR; the willingness to question one's own thoughts and analyze them in perspective) and self-certainty (SC; confidence in one's own thoughts and beliefs and resistance to correction). Higher SR scores are associated with lower psychotic symptoms and less distress, while higher SC scores are associated with cognitive rigidity (García-Mieres et al. 2020). In the UHR population, less attention has been paid to cognitive insight, but some results suggest that UHR individuals near the psychotic threshold tend to have lower SR and higher SC. These findings suggest that cognitive insight may influence the onset and severity of psychosis (Preti et al. 2022). Therefore, interventions targeting maladaptive metacognitions may help to prevent the progression to full-blown psychosis (Barkus et al. 2010).

Cognitive Behavioral Therapy (CBT) has been shown to reduce the risk of transition to psychosis in UHR patients (Devoe et al. 2020; Mei et al. 2021), but it has limited effects on attenuated psychotic symptoms or other general psychopathology (e.g., mood swings) (Devoe et al. 2020). This highlights the need for new interventions that address a broad range of symptoms (Mei et al. 2021; Rutigliano et al. 2016) and their common underlying mechanisms such as emotional dysregulation (McGorry et al. 2018), which are observed in both emotional (anxiety, depressive and related disorders) (Bullis et al. 2019) and psychotic spectrum disorders (Lawlor et al. 2020; Lincoln et al. 2017; Vines et al. 2021). Some studies suggest that interventions focusing specifically on emotional dysregulation and transdiagnostic therapies may be promising for UHR patients (Lincoln et al. 2017; Vines et al. 2021).

The Unified Protocol for the transdiagnostic treatment of emotional disorders (UP) focuses on emotional dysregulation, which is one of the transdiagnostic mechanisms that have been shown to be effective in treating a range of disorders in both individual (Eustis et al. 2020) and group formats (Peris-Baquero and Osma 2023; Reinholt et al. 2022). UP includes CBT techniques and third-wave techniques that have demonstrated their effectiveness in psychosis and UHR phase (McGorry et al. 2021; Peláez et al. 2024). Given these high comorbidity rates and the shared transdiagnostic mechanisms—especially emotional dysregulation—interventions such as the Unified Protocol (UP) appear theoretically and clinically justified for this population (Fusar-Poli et al. 2017; Lawlor et al. 2020; Peláez et al. 2022). The use of UP in psychosis is as yet uncommon, but it offers promising results. To our knowledge, only two studies have used UP in psychosis. Grasa et al. (Grasa et al. 2023) found positive results in a case report of resistant schizophrenia. In our group, we also found that UP improved anxiety and depressive symptoms in a sample of people with UHR (Peláez et al. 2024). However, there is no study investigating the effects of the UP intervention on cognitive distortions and cognitive insight in psychosis, although these variables are relevant for the treatment of the illness. To date, the efficacy of UP in metacognition in UHR patients have not been investigated.

The primary aim of this study was to investigate the effects of UP on the severity and distress of attenuated psychotic symptoms. The secondary aim was to assess the impact of UP on cognitive biases and cognitive insight in a sample of 36 individuals with UHR and emotional comorbidities.

## 2 | Methods

This is a secondary analysis of a pilot randomized controlled trial (RCT), which is described in detail in our study protocol paper (Peláez et al. 2022).

### 2.1 | Study Design and Participants

This was a two-condition RCT in which patients received either treatment with UP in addition to their treatment as usual (TAU; UP + TAU) or TAU alone. A set of randomly generated numbers was used for this purpose. The inclusion criteria were: (1) age between 18 and 35 years old, (2) a diagnosis of UHR with the CAARMS within the last 3 years and inclusion in our early intervention program, and (3) a diagnosis of a comorbid

emotional disorder with the MINI. In this study, we included the following emotional disorders: anxiety disorders, depressive disorders, bipolar and related disorders, obsessive-compulsive and related disorders, trauma and stress-related disorders, somatic symptoms and related disorders and substance-related and addictive disorders, or scores above the clinical cut-off points of the Beck Depression Inventory (Beck et al. 1996) and/or the Beck Anxiety Inventory (Beck et al. 1988) as a measure of depressive and anxiety symptoms, (4) fluent spanish/catalan, and (5) signed informed consent form. The exclusion criteria were (1) meeting criteria for a full-blown psychotic disorder according to the DSM in the past or in the present, (2) intellectual disability, and (3) an organic disorder that explains current symptomatology. The sample for this study consisted of 36 patients with a UHR diagnosis and symptoms of a DSM-5 comorbid emotional disorder who were receiving treatment in a community early intervention program for psychosis in Parc Sanitary Sant Joan de Déu and who agreed to participate in our study (Peláez et al. 2022).

Assessments were conducted at baseline, after the UP intervention and at the 3-month follow-up for all variables except CAARMS, assessed only at baseline and 3-month follow-up. Eighteen patients were randomized to the UP condition and a further 18 patients were randomized to the TAU condition. The UP intervention consisted of 15 weekly 2-h group sessions conducted online in co-therapy. Subjects were recruited from the community early intervention programs for psychosis whose reference center belongs to our institution, Parc Sanitari Sant Joan de Déu in Barcelona. A flowchart of the study can be found in Figure 1. This research has been evaluated and approved by the Ethics Committee for Drug Research (CEIm) of the Parc Sanitari Sant Joan de Déu. Participants received an information sheet explaining the objectives of the study, the procedures and the measures taken to protect the confidentiality of the data collected. In accordance with the Declaration of Helsinki (WMA 2013) and Law 14/2007 on Biomedical Research, written informed consent will be obtained from all participants. This study was registered on clinicaltrials.gov (Identifier number []).

## 2.2 | Interventions

In the UP condition, 15 online group sessions were conducted using the 2nd edition of the UP manuals (Barlow et al. 2011a; Barlow et al. 2011b) on the Zoom Premium platform.

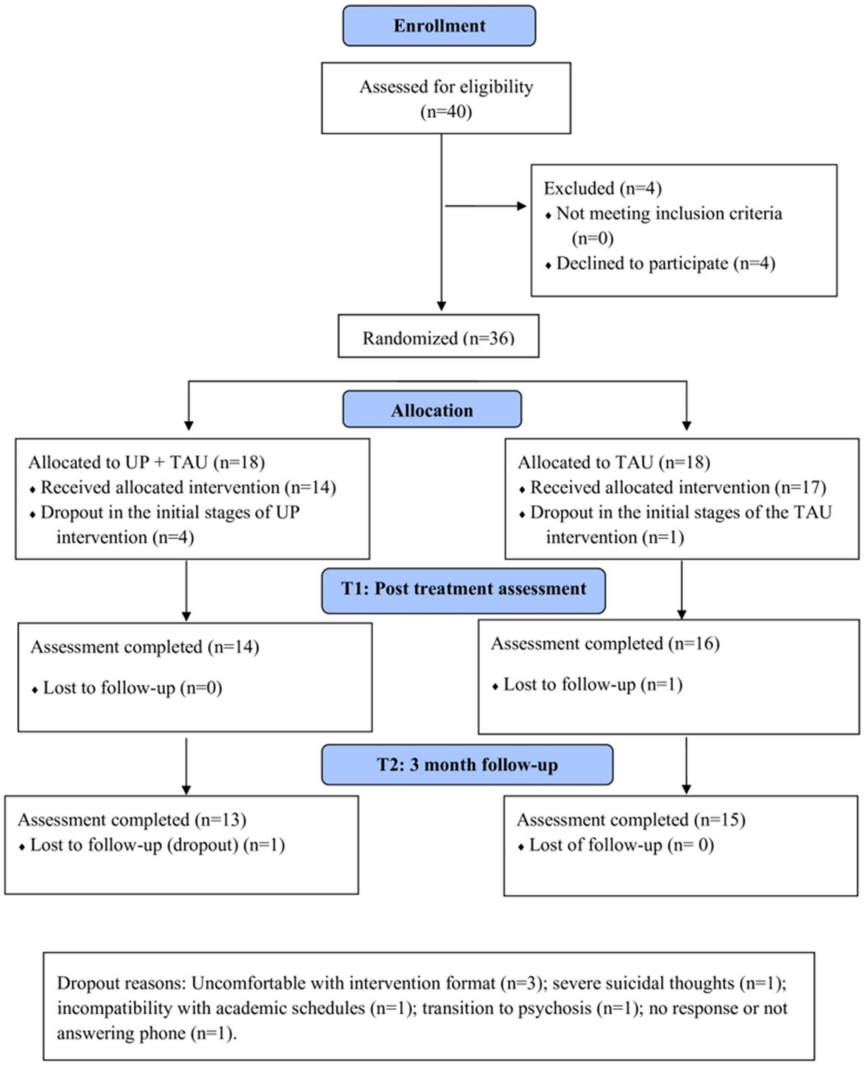


**FIGURE 1** | Study flowchart. *Note:* This figure was taken from (Blind note).

The UP groups had up to eight participants and were led by a therapist and a co-therapist who were trained in UP and initially supervised by a certified UP expert. Participants could switch off the camera if they felt uncomfortable and use the chat instead of the audio. The UP comprises 8 modules that progressively address setting goals and maintaining motivation, psychoeducation about emotions, mindful awareness, cognitive flexibility, countering emotional behaviors, tolerance of physical sensations, emotional exposure, and relapse prevention. Together, these modules target core processes of emotional dysregulation through cognitive, behavioral, and experiential strategies. In individuals with psychotic symptoms, UP techniques may help reduce distress by enhancing tolerance of intense emotional states and promoting more flexible interpretations of internal experiences, thereby supporting adaptive emotion regulation and cognitive flexibility. The modules were covered in weekly 2-h sessions over a period of approximately 4 months. The detailed objectives and content of the modules can be found in the supplementary material (Table 5). Two follow-up sessions took place 1 month and 3 months after the end of the group intervention.

TAU comprised a multidisciplinary early intervention program for psychosis with psychological therapy (20–40 CBT sessions weekly or fortnightly), psychiatric treatment (with necessary medication), social work (occupational support), nursing care (monitoring side effects and promoting healthy habits), individual cognitive remediation (if needed), and family therapy. The frequency and content of the TAU sessions were individualized for each patient. Some participants were receiving pharmacological treatment as part of standard care, mainly antidepressant medication, with a few also taking low doses of antipsychotics. Randomization ensured that participants were evenly distributed across both study conditions in terms of medication use and type.

## 2.3 | Measures

The Comprehensive Assessment of At-Risk Mental States (CAARMS) (Yung et al. 2005). This is a semi-structured assessment interview to identify young people seeking help who are at ultra-high risk of psychosis. It assesses the severity, frequency, and level of distress caused by these symptoms. The abbreviated Spanish version of the CAARMS was used, which focuses on the positive symptom subscales (unusual thought content, non-bizarre ideas, perceptual abnormalities, disorganized speech). The severity of CAARMS symptoms was measured by totaling the products of the global rating scale score (0–6) and the frequency (0–6) for the four subscales. The range of totaled scores was between 0 and 144, and distress was measured as the average distress score (0–100) for the four subscales (Morrison et al. 2012)[38]. The CAARMS has a very high inter-rater reliability (0.85).

Cognitive Biases Questionnaire for Psychosis (CBQp) (Corral et al. 2020; Peters et al. 2014). This questionnaire consists of 30 statements covering two different vignette topics: 15 relate to anomalous perceptions (AP) and the other 15 to threatening events (TE). Each group of statements covers five cognitive biases: intentionality, catastrophism, dichotomous thinking, jumping to conclusions, and emotional reasoning. Each statement is scored on a scale of 1–3 (1 = no bias; 2 = bias with some reservations; and 3 = bias). The total score for each topic is 45, and the maximum total score is 90. The potential range of scores for each theme was between 15 and 45, and for each bias it was between 6 and 18. Higher scores indicate a more pronounced bias. Cronbach's alpha of the total CBQp was 0.89; 0.76 for the AP scale and 0.78 for the TE scale.

Beck Cognitive Insight Inventory (BCIS) (Beck 2004; Gutiérrez-Zotes et al. 2012). This is a self-assessment instrument consisting of 15 items that patients can use to evaluate their own judgment. It comprises two dimensions: Self-Reflectiveness (SR; patients' ability to observe their own thoughts and consider alternative explanations) with nine items and Self-Certainty (SC; their overconfidence in the validity of their beliefs) with six items. A composite index (CI) reflecting cognitive insight is calculated as SR minus SC (CI = SR-SC). The response format includes four Likert-type options: Never Agree (0), Somewhat Agree (1), Quite Agree (2), and Totally Agree (3), with a total score between 0 and 45. Higher scores on SR and the CI indicate greater cognitive insight, while lower scores on self-confidence indicate better cognitive insight. The internal consistency of the Spanish validation of the BCIS was 0.59 for SR and 0.62 for SC.

## 2.4 | Sample Size Calculation

The sample size was determined a priori to obtain effect sizes of 1 with a statistical power of 80% in a bilateral *t*-test, assuming a significance level of 0.05 and an expected loss to follow-up of 20%. It was estimated that a total of 21 patients were required for each condition. An article by Barlow from 2017 was used as a reference for this calculation (Barlow et al. 2017). This calculation was based on the primary outcomes (anxiety and depressive symptoms assessed with the BDI-II and BAI). Secondary variables (CAARMS, CBQp, BCIS) were included for exploratory purposes and were not specifically considered in the a priori power analysis.

## 2.5 | Statistical Analysis

All statistical analyses were carried out using the intention-to-treat sample ($n = 36$). Descriptive analysis of participants' data was performed, including frequencies and percentages for categorical variables and means and standard deviations for numerical variables. All *p*-values reported were unadjusted for multiple comparisons, consistent with the exploratory nature of the study. Linear mixed models were used to examine progression over time in both groups. These models included fixed effects for time, group, and their interaction, as well as a random effect associated with subject ID. Homoscedasticity and normality of the residuals were checked to ensure appropriate model fitting. When residuals did not meet these assumptions, robust estimating equations were used to compute the linear mixed effects. A significance level of 0.05 was used. Analyses were conducted using R version 4.3.1 and RStudio version 2022.02.0 + 443. The linear and logistic mixed models were created using the R packages lme4 (v. 1.1-34) and lmerTest (v. 3.1-3), while robust linear mixed models were created

**TABLE 1** | Sociodemographic characteristics of the sample.

| | | Mean (SD) | |
|---|---|---|---|
| | | UP + TAU | TAU |
| Age | | 21.7 (3.37) | 24.8 (4.81) |
| | | N (%) | |
| Gender | Female | 11 (61.1%) | 7 (38.9%) |
| | Male | 6 (33.3%) | 11 (61.1%) |
| | Others | 1 (5.6%) | 0 (0%) |
| Educational level | Primary | 3 (5.6%) | 4 (0%) |
| | Secondary | 14 (44.4%) | 9 (22.2%) |
| | University completed | 1 (5.6%) | 5 (27.8%) |
| Living situation | Family of origin | 17 (47.2%) | 12 (33.3%) |
| | Independent | 1 (2.8%) | 5 (13.9%) |
| | Others | 0 (0%) | 1 (2.8%) |
| Number of siblings | 0 | 4 (11.1%) | 1 (2.8%) |
| | 1 | 11 (30.6%) | 9 (25%) |
| | 2 | 2 (5.6%) | 4 (11.1%) |
| | 3 | 1 (2.8%) | 4 (11.1%) |

using the package robustlmm (v. 0.99-0). The partial $R^2$ was calculated to measure the effect size for the fixed effects in the mixed model using the package r2glmm (Cohen 2013; Jaeger et al. 2016).

Given the exploratory and pilot nature of this study, no corrections for multiple comparisons were applied. Applying strict alpha adjustments in small samples can substantially reduce statistical power and increase the risk of type II errors (Bender and Lange 2001). Therefore, *p*-values were reported unadjusted, and results should be interpreted with caution.

**TABLE 2** | Comorbid emotional disorders, grouped by category.

| | UP + TAU N (%) | TAU N (%) |
|---|---|---|
| Depressive disorders | 11 (34.4%) | 10 (30.3%) |
| Suicidal behavior | 5 (15.6%) | 2 (6.1%) |
| Bipolar disorders | 4 (12.5%) | 4 (12.1%) |
| Anxiety disorders | 19 (59.4%) | 19 (57.6%) |
| Substance use disorders | 10 (31.2%) | 14 (42.4%) |
| Eating disorders | 8 (25%) | 1 (3%) |

## 3 | Results

### 3.1 | Sociodemographic and Baseline Data

The sociodemographic data of the participants in this study are shown in Table 1. The average age of the participants was 23 years (21.7 years for the participants in the UP condition; 24.8 years for the participants in the TAU condition) and most of them lived with their family of origin.

Regarding the UHR baseline diagnosis, the majority of the total sample (86%) met criteria for the attenuated psychosis subgroup. The other UHR subtypes were less well represented. Only 5% of the sample met criteria for the genetic risk type and 3% for brief limited and intermittent psychotic symptoms (BLIPS). A more detailed description of the individual UHR psychosis groups in our sample can be found in the supplementary material (Figure 2).

The majority of the total sample (94.3%) had at least one comorbid emotional disorder at baseline, which was measured using the MINI (Sheehan et al. 1998). Table 2 shows the prevalence of each diagnostic category in the two groups of patients. The descriptive statistics of all the measures are shown in Table 3. No differences were detected in any of the clinical measures between the two groups of patients at baseline (see UP coefficients at mixed models in Table 4).

### 3.2 | Attenuated Psychotic Symptoms

In terms of severity of attenuated psychotic symptoms, none of the effects were significant, and we did not detect changes in either group during post-treatment or at the 3-month follow-up. The interaction between time and group showed that the distress scores of the CAARMS of the patients in the UP group evolved significantly differently over time from those of the control group ($T0\text{-}T2_{(\text{interaction with TAU})}$: estimate = −20.90, SE = 8.70, $p = 0.02$). On the other hand, the model did not detect any overall change from baseline to 3-month follow-up (T0-T2: estimate = −0.82, SE = 6.03, $p = 0.89$). Thus, these results suggest that the severity of psychotic attenuated symptoms decreased in UP + TAU patients, whereas it remained unchanged in TAU patients. Small effect sizes were detected in the distress scores for the

**TABLE 3** | Descriptive statistics of the variables for the two groups at the three evaluation points.

| | | UP + TAU | | TAU | |
|---|---|---|---|---|---|
| **Measures** | **Timepoint** | **M** | **SD** | **M** | **SD** |
| CAARMS_severity | Baseline | 59.6 | 23.6 | 52.2 | 29.2 |
| | 3 M | 34 | 25.2 | 40.4 | 21.5 |
| CAARMS_distress | Baseline | 54.6 | 21.1 | 41 | 22 |
| | 3 M | 33.2 | 20.3 | 39.8 | 22.6 |
| CBQp_total | Baseline | 47.9 | 7.08 | 48.7 | 8.67 |
| | Post | 43.1 | 11.6 | 49.9 | 10.6 |
| | 3 M | 41.2 | 8.21 | 48.8 | 9.92 |
| CBQp_TE | Baseline | 26.3 | 4.62 | 25.9 | 4.54 |
| | Post | 23.1 | 5.94 | 27 | 6.18 |
| | 3 M | 22.6 | 4.74 | 26.2 | 5.00 |
| CBQp_AP | Baseline | 21.6 | 3.16 | 22.8 | 5.16 |
| | Post | 20.0 | 6.05 | 22.9 | 5.51 |
| | 3 M | 18.5 | 4.16 | 22.6 | 5.42 |
| CBQp_Int | Baseline | 8.28 | 1.49 | 8.11 | 1.94 |
| | Post | 8.18 | 1.66 | 8.53 | 1.81 |
| | 3 M | 7.62 | 1.90 | 8.62 | 2.36 |
| CBQp_Cat | Baseline | 9.67 | 2.22 | 10.3 | 2.30 |
| | Post | 8.54 | 2.25 | 10.5 | 2.75 |
| | 3 M | 8.31 | 1.93 | 10.2 | 2.44 |
| CBQp_DT | Baseline | 9.83 | 2.20 | 9.72 | 2.72 |
| | Post | 9.36 | 3.50 | 10.8 | 3.08 |
| | 3 M | 8.77 | 2.49 | 9.5 | 2.28 |
| CBQp_JTC | Baseline | 10.9 | 1.84 | 11.1 | 2.26 |
| | Post | 9.09 | 2.26 | 10.5 | 2.67 |
| | 3 M | 9 | 2.20 | 11.2 | 2.81 |
| CBQp_ER | Baseline | 9.11 | 1.97 | 9.17 | 1.79 |
| | Post | 7.64 | 2.25 | 9.4 | 2.13 |
| | 3 M | 7.31 | 1.70 | 9 | 2.42 |
| BCIS_total | Baseline | 6.24 | 6.81 | 6.28 | 4.65 |
| | Post | 7.64 | 8.52 | 7.87 | 5.19 |
| | 3 M | 7.31 | 7.70 | 6.44 | 5.23 |
| BCIS_SR | Baseline | 13.88 | 4.82 | 14.3 | 3.69 |
| | Post | 15.09 | 5.74 | 15.5 | 4.96 |
| | 3 M | 14.69 | 5.60 | 14.4 | 4.18 |
| BCIS_SC | Baseline | 7.65 | 3.87 | 8.06 | 3.89 |
| | Post | 7.46 | 3.24 | 7.67 | 2.87 |
| | 3 M | 7.38 | 3.25 | 8 | 2.56 |

Abbreviations: 3 M, 3-month follow-up evaluation; Baseline, Baseline evaluation; Cat, Catastrophism; CAARMS, Comprehensive Assessment of At Risk Mental States; CBQp, Cognitive Biases Questionnaire for Psychosis scale; DT, Dichotomous Thinking; ER, Emotional Reasoning BCIS, Beck Cognitive Insight Inventory; Int, Intentionality; JTC, Jumping to Conclusions; M, Mean; PA, Anomalous Perception; Post, Post-treatment evaluation; SC, Self-Certainty; SD, Standard deviation; SE, Standard error; SR, Self-Reflectiveness; TE, Threatening Events; UP + TAU, UP plus TAU.

interaction between the two conditions at the 3-month follow-up. We found only one patient from the total sample who transitioned to psychosis according to the CAARMS criteria, belonging to the TAU group. All these data are provided in Table 4.

### 3.3 | Cognitive Biases

As can be seen in Table 4, the evolution of CBQ total scores differs significantly between the groups along T0 and T1 (T0-$T1_{(\text{interaction with UP})}$: estimate = −6.38, SE = 2.08, $p = 0.003$) or T0 and T2 T0-$T2_{(\text{interaction with UP})}$: estimate = −5.57, SE = 1.98,

**TABLE 4** | Results of mixed effect models for all the variables.

| Measures | Fixed effects | Estimate | SE | Df | *t* value | *p* value | Effect size R2 |
|---|---|---|---|---|---|---|---|
| CAARMS_severity | Intercept | 52.24 | 6.07 | 56.75 | 8.61 | < 0.001 | |
| | T2 | −11.90 | 7.34 | 30.50 | −1.62 | 0.12 | 0.031 |
| | UP | 7.32 | 8.46 | 56.75 | 0.87 | 0.39 | 0.013 |
| | T2 UP* | −14.49 | 10.58 | 31.84 | −1.37 | 0.18 | 0.022 |
| CAARMS_distress | Intercept | 41.03 | 5.22 | 54.77 | 7.86 | < 0.001 | |
| | T2 | −0.82 | 6.03 | 29.74 | −0.14 | 0.89 | 0.000 |
| | UP | 13.55 | 7.28 | 54.77 | 1.86 | 0.07 | 0.056 |
| | T2 UP* | −20.90 | 8.70 | 31.00 | −2.40 | 0.02* | 0.061 |
| CBQ_p_total** | Intercept | 48.39 | 2.18 | | 22.15 | < 0.001 | |
| | T1 | 1.10 | 1.37 | | 0.81 | 0.42 | 0.003 |
| | T2 | 0.01 | 1.33 | | 0.01 | 0.99 | 0.001 |
| | UP | −0.86 | 3.09 | | −0.28 | 0.78 | 0.001 |
| | T1 UP* | −6.38 | 2.08 | | −3.07 | 0.003* | 0.027 |
| | T2 UP* | −5.57 | 1.98 | | −2.81 | 0.006* | 0.037 |
| CBQ_p_TE ** | Intercept | 25.69 | 1.22 | | 21.03 | < 0.001 | |
| | T1 | 0.62 | 0.85 | | 0.73 | 0.47 | 0.003 |
| | T2 | 0.29 | 0.83 | | 0.35 | 0.73 | 0.001 |
| | UP | 0.35 | 1.73 | | 0.20 | 0.84 | 0.001 |
| | T1 UP* | −3.50 | 1.29 | | −2.71 | 0.009* | 0.031 |
| | T2 UP* | −3.16 | 1.23 | | −2.57 | 0.013* | 0.033 |
| CBQ_p_AP ** | Intercept | 22.39 | 1.15 | | 19.48 | < 0.001 | |
| | T1 | 0.63 | 0.82 | | 0.77 | 0.45 | 0.002 |
| | T2 | −0.11 | 0.80 | | −0.14 | 0.89 | 0.001 |
| | UP | −0.88 | 1.63 | | −0.54 | 0.59 | 0.009 |
| | T1 UP* | −2.94 | 1.25 | | −2.36 | 0.02* | 0.014 |
| | T2 UP* | −2.55 | 1.19 | | −2.14 | 0.04* | 0.027 |
| CBQ_p_Int ** | Intercept | 8.00 | 0.41 | | 19.64 | < 0.001 | |
| | T1 | 0.38 | 0.50 | | 0.75 | 0.46 | 0.005 |
| | T2 | 0.33 | 0.49 | | 0.67 | 0.51 | 0.011 |
| | UP | 0.15 | 0.58 | | 0.26 | 0.79 | 0.001 |
| | T1 UP* | −0.43 | 0.76 | | −0.57 | 0.57 | 0.004 |
| | T2 UP* | −0.97 | 0.72 | | −1.34 | 0.19 | 0.020 |
| CBQ_p_Cat** | Intercept | 10.34 | 0.62 | | 16.63 | < 0.001 | |
| | T1 | 0.39 | 0.44 | | 0.90 | 0.37 | 0.003 |
| | T2 | −0.06 | 0.42 | | −0.15 | 0.88 | 0.000 |
| | UP | −0.76 | 0.88 | | −0.86 | 0.39 | 0.012 |
| | T1 UP* | −1.32 | 0.66 | | −2.00 | 0.05* | 0.022 |
| | T2 UP* | −1.00 | 0.63 | | −1.58 | 0.12 | 0.020 |
| CBQ_p_DT | Intercept | 9.72 | 0.62 | 47.86 | 15.62 | < 0.001 | |
| | T1 | 1.08 | 0.51 | 53.09 | 2.13 | 0.04* | 0.024 |
| | T2 | −0.00 | 0.49 | 52.85 | −0.01 | 0.99 | 0.000 |
| | UP | 0.11 | 0.88 | 47.86 | 0.13 | 0.90 | 0.000 |
| | T1 UP* | −1.64 | 0.77 | 54.36 | −2.13 | 0.04* | 0.025 |
| | T2 UP* | −1.01 | 0.73 | 54.01 | −1.38 | 0.17 | 0.010 |
| CBQ_p_JTC** | Intercept | 11.02 | 0.52 | | 21.14 | < 0.001 | |
| | T1 | −0.88 | 0.46 | | −1.89 | 0.06* | 0.008 |

(Continues)

**TABLE 4** | (Continued)

| Measures | Fixed effects | Estimate | SE | Df | *t* value | *p* value | Effect size R2 |
|---|---|---|---|---|---|---|---|
| | T2 | −0.11 | 0.45 | | −0.24 | 0.81 | 0.001 |
| | UP | −0.11 | 0.74 | | −0.15 | 0.88 | 0.001 |
| | T1 UP* | −0.94 | 0.70 | | −1.34 | 0.19 | 0.012 |
| | T2 UP* | −1.58 | 0.67 | | −2.36 | 0.02* | 0.041 |
| CBQ_p_ER** | Intercept | 9.09 | 0.49 | | 18.47 | < 0.001 | |
| | T1 | 0.30 | 0.44 | | 0.69 | 0.49 | 0.002 |
| | T2 | −0.26 | 0.43 | | −0.61 | 0.54 | 0.000 |
| | UP | −0.05 | 0.70 | | −0.07 | 0.95 | 0.000 |
| | T1 UP* | −1.69 | 0.66 | | −2.57 | 0.01* | 0.030 |
| | T2 UP* | −1.12 | 0.63 | | −1.77 | 0.08 | 0.025 |
| BCIS_total | Intercept | 6.28 | 1.47 | 41.80 | 4.27 | < 0.001 | |
| | T1 | 1.59 | 0.96 | 51.13 | 1.66 | 0.10 | 0.012 |
| | T2 | −0.43 | 0.93 | 51.00 | −0.46 | 0.65 | 0.001 |
| | UP | 0.01 | 2.09 | 42.47 | 0.01 | 1.00 | 0.000 |
| | T1 UP* | 0.05 | 1.46 | 51.97 | 0.04 | 0.97 | 0.000 |
| | T2 UP* | 1.04 | 1.41 | 52.39 | 0.74 | 0.46 | 0.002 |
| BCIS_SR** | Intercept | 14.13 | 1.15 | | 12.25 | < 0.001 | |
| | T1 | 1.41 | 0.80 | | 1.76 | 0.85 | 0.010 |
| | T2 | 0.05 | 0.78 | | 0.07 | 0.95 | 0.000 |
| | UP | −0.24 | 1.64 | | −0.15 | 0.89 | 0.002 |
| | T1 UP* | 0.50 | 1.22 | | 0.41 | 0.68 | 0.001 |
| | T2 UP* | 0.87 | 1.19 | | 0.73 | 0.47 | 0.003 |
| BCIS_SC | Intercept | 8.06 | 0.79 | 46.39 | 10.20 | < 0.001 | |
| | T1 | −0.43 | 0.63 | 51.53 | −0.69 | 0.49 | 0.003 |
| | T2 | 0.38 | 0.62 | 51.31 | 0.62 | 0.54 | 0.002 |
| | UP | −0.45 | 1.12 | 47.32 | −0.40 | 0.69 | 0.003 |
| | T1 UP* | 0.57 | 0.96 | 52.76 | 0.60 | 0.55 | 0.002 |
| | T2 UP* | −0.13 | 0.93 | 53.27 | −0.14 | 0.89 | .000 |

Abbreviations: 3 M, 3-month follow-up evaluation; Baseline, Baseline evaluation; CAARMS, Comprehensive Assessment of At Risk Mental States; Cat, Catastrophism; CBQp, Cognitive Biases Questionnaire for Psychosis scale; DT, Dichotomous Thinking; ER, Emotional Reasoning BCIS, Beck Cognitive Insight Inventory; Int, Intentionality; JTC, Jumping to Conclusions; PA, Anomalous Perception; Post, Post-treatment evaluation; SC, Self-Certainty; SE, Standard error; SR, Self-Reflectiveness; T1, Post treatment assessment; T2, 3-month follow-up assessment; TE, Threatening Events; UP, Unified Protocol.
*Statistically significant differences between the two conditions.
**Robust analyses were performed.

$p = 0.007$). The same effect was observed in the AP subscale (T0-T1$_{(\text{interaction with UP})}$: estimate = −2.94, SE = 1.25, $p = 0.02$; T0-T2$_{(\text{interaction with UP})}$: estimate = −2.55, SE = 1.19, $p = 0.04$) and the TE subscale (T0-T1$_{(\text{interaction with UP})}$: estimate = −3.50, SE = 1.29, $p = 0.009$; T0-T2$_{(\text{interaction with UP})}$: estimate = −3.16, SE = 1.23, $p = 0.01$). No significant changes were observed in these values from T0 to T1 or from T0 to T2, so that the interactions indicate that there were only improvements in these areas in the UP + TAU patients. The $R^2$ values showed small effect sizes for the interaction on the two main subscales and the total score.

Regarding the specific cognitive biases, the model found differences for both groups at post-treatment assessment in catastrophising (T0-T1$_{(\text{interaction with UP})}$: estimate = −1.32, SE = 0.66, $p = 0.05$), emotional reasoning (T0-T1$_{(\text{interaction with UP})}$: estimate = −1.69, SE = 0.66, $p = 0.01$), and, at the 3-month follow-up, in JTC (T0-T2$_{(\text{interaction with UP})}$: estimate = −1.58, SE = 0.67, $p = 0.02$). Since we have no significant results at T0-T1 for catastrophism (T0-T1: estimate = 0.39, SE = 0.44, $p = 0.37$) and emotional reasoning (T0-T1: estimate = 0.30, SE = 0.44, $p = 0.49$), or from T0 to T2 in JTC (T0-T2: estimate = −0.11, SE = 0.45, $p = 0.81$), these significant interactions suggest that there was an improvement in the UP + TAU group that does not occur in the TAU group. On the other hand, the model detected significant differences in the change in dichotomous thinking between the pre- and post-treatment measurements for both groups (T0-T1$_{(\text{interaction with UP})}$: estimate = −1.64, SE = 0.77, $p = 0.04$). Together with the significant increase in total scores between these time points (T0-T1: estimate = 1.10, SE = 0.51, $p = 0.04$), these results suggest that participants in the TAU group showed an increase in dichotomous thinking bias, whereas these scores did not change for the UP + TAU patients.

The overall non-significant changes between these time periods and these significant interactions indicated an improvement in patient scores in the UP + TAU condition that was not observed in the TAU group.

### 3.4 | Cognitive Insight

No changes over time were observed in the Composite Index or in the SC or SR subscales in either group. All these data can be seen in Table 4.

## 4 | Discussion

To our knowledge, this is the first study to examine the effects of the UP, a transdiagnostic CBT-based psychological intervention focused on training adaptive emotion regulation strategies, on attenuated psychotic symptoms, cognitive biases, and cognitive insight in individuals with UHR and emotional comorbidities.

Regarding the CAARMS scores, our results suggest that the UP may be an effective intervention for reducing the emotional distress caused by attenuated psychotic symptoms, regardless of their severity or frequency. This may mean that the emotion regulation strategies specifically worked on in the UP sessions reduced patients' suffering and the interference with their daily lives. In the first clinical trial using manualized and individual CBT in patients with UHR (Morrison et al. 2012), the effect of the intervention on attenuated psychotic symptoms was secondarily analyzed and opposite results were found. There was a reduction in the severity of attenuated psychotic symptoms, but no changes in associated distress were observed. This supports the hypothesis that the UP intervention could be of clinical benefit to complement and enhance the positive results previously obtained with protocolized and individualized CBT, possibly due to its reducing symptom-induced distress. A possible explanation for these differences lies in the fact that UP includes an emotion-focused psychoeducation module, motivational interviewing, and acceptance-based techniques, and emotional experience acceptance techniques, alongside other traditional CBT skills such as cognitive flexibility and exposure. The reduction in distress due to attenuated psychotic symptoms found in our study is similar to the results of a previous study in which CBT was enriched with psychoeducation about dopamine hypersensitivity and cognitive distortions in patients with UHR (van der Gaag et al. 2012).

In our study, there was only one case of transition to psychosis in the entire sample during the 3-month follow-up period. As confirmed in previous studies, the rate of transition to psychosis in patients with UHR treated in specialized services has decreased from 40% to 22% compared to the first studies (Mei et al. 2021). This may be due to the fact that early-stage psychosis services are now better able to detect new cases of UHR and also that the quality of interventions has improved as a result of the many research studies that have been conducted over the past 25 years. However, this result should be treated with caution, as the follow-up period is short and the sample small. In addition to considering "transition to psychosis" as an outcome variable, we believe it is very important to consider remission of attenuated psychotic symptoms as one of the main goals of interventions for young people with UHR. The persistence of attenuated psychotic symptoms has been associated with a significantly worse clinical profile (compared to remitted cases), characterized by lower levels of functioning and more severe negative, anxious, and depressive symptoms (Spiteri-Staines et al. 2024). Furthermore, we believe that targeted treatment of comorbid anxiety and depressive symptoms could significantly improve prognosis, as their impact on long-term functioning has been demonstrated (Albert et al. 2018; Polari et al. 2018).

We also think it is important to emphasize the improvement in cognitive biases found in our study. Both TE and AP are considered areas of great importance in psychosis, as there is a relationship between them and the presence, belief, distress, and preoccupation with delusions and positive and depressive symptoms (Ahuir et al. 2021; Corral et al. 2020). Moreover, these biases are more prevalent in individuals with psychosis compared to healthy participants, and even more pronounced in individuals with greater symptom severity (Peters et al. 2014). The UP modules involving cognitive work, that is, training emotional awareness (including thoughts) in the present moment without judgment and cognitive flexibility, may have had an impact on reducing psychosis-specific cognitive biases, as did the module on recognizing and analyzing emotional experiences. In these three modules, patients are trained to recognize and observe their emotional experiences and their different components (thoughts, physical sensations and emotion-driven behaviors) without reacting to them in order to develop alternative thoughts that reduce their negative impact so that they can choose the appropriate behavior that corresponds to their goals.

The strong reduction in emotional reasoning bias in the UP condition (after treatment and at the 3-month follow-up) appears to be of great clinical value, as previous studies have found a specific association between this bias and susceptibility to auditory verbal hallucinations (Daalman et al. 2013). One possible explanation for these findings is that patients who participate in the UP intervention become more aware of the role their emotions play in certain situations and therefore use emotion regulation skills to consider alternative interpretations and behaviors before acting. This makes sense, as UP is a transdiagnostic intervention focused on improving emotional dysregulation.

We note that the significant decrease in JTC at the 3-month follow-up is also a result to be taken into account. JTC is the only specific cognitive bias consistently found in studies with psychotic spectrum disorders and UHR samples (Gawęda et al. 2024). The association between stress and JTC has already been demonstrated (Moritz et al. 2012; Moritz et al. 2015) and for this reason UP could be a comparable intervention to others that have shown specific improvements in JTC bias (Ward and Garety 2017).

With regard to the various dimensions of cognitive insight, we were unable to detect changes in either of the two study conditions. These findings contrast with the results of previous studies that have demonstrated the efficacy of other evidence-based psychological interventions in samples of patients with early psychosis (Lopez-Morinigo et al. 2020). Specifically, in

patients with first-episode of psychosis, Ochoa et al (Ochoa et al. 2017) found that those in metacognitive training (Moritz et al. 2013) (MCT) improved in overall BCIS both after treatment and at 6-month follow-up in the experimental group compared to an active control condition (psychoeducational treatment). One possible explanation of this is that in our sample of UHR patients, baseline cognitive insight scores were worse, which could be one of the reasons why the improvement from the intervention was not as great. Another possible explanation is the lack of specific content on metacognitive aspects of the UP intervention. To improve our results in terms of cognitive insight in the future, some MCT sessions could be included in the UP intervention, especially those that have been shown to be particularly effective in reducing SC as measured with the BCIS (Birulés et al. 2020). One option would be to include content from the empathy domain (to raise awareness that other people have different views than oneself) or specific modules of the MCT (such as memory, cognitive flexibility and theory of mind) or a module on interpersonal emotion regulation. Given the versatility and modular format of the UP and MCT interventions, we believe that this is entirely feasible.

As the main limitation of our study, we consider it important to emphasize the small sample size. This is partly due to the fact that the groups were formed consecutively and it was difficult to extend the recruitment period further. In addition, the number of patients recruited did not reach the estimated sample size calculated before the start of the study. Although significant results were obtained for most of the study variables, no corrections were made to the *p*-values, as was the case in previous studies with small sample sizes (Bender and Lange 2001). Because no corrections for multiple comparisons were applied, the possibility of inflated type I error cannot be ruled out. For all these reasons, we believe that the results should be interpreted with caution and may be considered as a first application of UP in this type of patients to test its feasibility and justify future clinical trials with larger sample sizes. We also emphasize that this RCT is an underpowered pilot study. The second limitation of our study is the short follow-up period. If the follow-up period had been longer, we would have been able to determine whether the treatment effects were maintained in the long term, as previous studies in the field of emotional disorders have shown (Bullis et al. 2019). Finally, the large number of self-reported measures could increase subjectivity in the interpretation of the results of our study. These limitations should be considered when designing future studies with similar samples.

The results of our study seem to us to be of great clinical value, as they open the door to transdiagnostic interventions that have been shown to be cost-effective (Peris-Baquero et al. 2022) and that can be implemented in public mental health services for young people seeking help for potentially severe subthreshold symptoms with negative effects on long-term functioning (stages 1a and 1b) (McGorry et al. 2018). Our findings are consistent with a growing body of evidence suggesting that the aetiology, manifestation, and treatment of mental illness are largely transdiagnostic (van Os et al. 2023). The UP is a transdiagnostic intervention that may fit this new paradigm of mental illness as a continuum model rather than a categorical model.


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## Data Availability Statement

The authors have nothing to report.

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## Supporting Information

Additional supporting information can be found online in the Supporting Information section.
**Table 5:** Modules and sessions of the UP. **Figure 2:** Percentages of each UHR subtype of the total sample.