Acceptability of and Intention to use the Unified Protocol delivered in group format in the Spanish Public Health System

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Data Availability Statement

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

Conflict of Interest

The authors declare that they have no conflict of interest.

57 ***Keywords**: Unified Protocol, Acceptability, Group format, Therapists, SWOT, Public*
58 *Health.*

59
Introduction

60 The United Nations Organization[1] emphasizes the need to assume policies that
61 guarantee sustainable development. Thus, goal 3 of the United Nations, Health and Well-
62 Being of the Sustainable Development Agenda 2030, specifies the importance of
63 guaranteeing a "universal, public and free access to the health system, as well as ensuring its
64 sustainability”. This goal is very important for National Public Health Systems due to their
65 limited resources.

66 If we focus only on mental health data, in 2017, approximately 284 million people
67 were suffering from some anxiety disorder and 264 million from depression, which
68 represents between 3.8% and 3.4% of the world's population[2]. In addition to their high
69 prevalence, depression and anxiety disorders, also called emotional disorders (EDs)[3], present
70 a high rate of current and lifetime comorbidity[4]. These characteristics cause an increased
71 demand for psychological care and, as a consequence, the collapse of the Spanish public
72 health system[5]. This is observed in the long waiting lists[6], the long time between
73 appointments[7], and the direct and indirect costs for the treatment of EDs (economic, material,
74 and human resources), around 45 billion euros per year, which represents the 4.2% of the
75 Spanish Gross Domestic Product[8]. Thus, it is very important to offer economically, socially
76 and sustainable mental health services and to continuously evaluate them to ensure the correct
77 incorporation and use of evidence-based and sustainable interventions[9].

78 A possible solution to the aforementioned collapse of the Spanish Health System
79 regarding mental health care could be the use of psychological transdiagnostic interventions.
80 The transdiagnostic approach suggests that EDs share etiological and maintenance factors

81 (e.g., high neuroticism), which could also explain their high comorbidity[10]. From this
82 perspective, it is possible to identify these common factors and to develop a unique
83 psychological intervention for all of them. On the basis of these assumptions, David H.
84 Barlow and his team have developed the Unified Protocol for the Transdiagnostic Treatment
85 of Emotional Disorders (hereinafter, UP[11]).The UP is an emotion-regulation-based
86 intervention that has demonstrated its effectiveness for the treatment of all ranges of EDs,
87 including those cases presenting comorbidity and those with depressive or anxiety subclinical
88 symptoms[12,13]. In addition, the UP can be delivered in a group format, increasing its cost-
89 efficiency[14,15]. The transdiagnostic nature of the treatment facilitates a quick group
90 formation, allowing clinicians to attend to a greater number of people at the same time, as a
91 consequence, reducing the waiting lists[16]. However, in addition to the efficiency and
92 effectiveness of the UP, other aspects such as its acceptability should be also evaluated.

93 Interest in assessing the acceptability of healthcare interventions has been increasing
94 in recent years, especially as a necessary feature for proper implementation[17,18]. Nevertheless,
95 the diversity of definitions and recommendations on how to assess the acceptability of
96 healthcare interventions has made this task difficult[19]. To address this, the Theoretical
97 Framework of Acceptability (TFA[19]) has recently emerged based on a systematic review,
98 which assesses acceptability and unifies approaches into a single theoretical framework. This
99 model is composed of seven constructs: [1] Affective Attitude (how an individual feels about
100 the intervention); [2] Burden (the perceived amount of effort that is required to participate
101 in the intervention); [3] Ethicality (the extent to which the intervention fits an individual's
102 value system); [4] Intervention coherence (the extent to which the participant understands
103 the intervention and how it works); [5] Opportunity Costs (the extent to which benefits,
104 profits or values must be given up to engage in the intervention); [6] Perceived effectiveness
105 (the extent to which the intervention is perceived as likely to achieve its purpose); and [7]

106 Self-efficacy (the participants' confidence that they can perform the behavior required to
107 participate in the intervention).

108 The evaluation of the effectiveness and acceptability of interventions in health
109 systems contributes to improving their quality and facilitates treatment commitment and
110 adherence[20,21]. For this purpose, it is necessary to encourage the active role of patients and
111 professionals to know their opinion of the services they receive or apply. Regarding patients,
112 previous studies have analyzed the acceptability of the UP in patients finding generally high
113 levels of acceptance and satisfaction. For example, Bentley et al[22] showed that 82% of the
114 patients scored as "very" or "extremely" acceptable the UP and 69% reported "very" or
115 "extremely" satisfaction. Similar results were found by Osma et al[23] with high satisfaction
116 ratings (M = 3.59, SD = 0.40, range 0-4) and by Sauer-Zavala et al[24] showing scores of "very
117 acceptable" (M = 4.83, SD = 0.39, range 0-5) and "quite satisfied" (M = 4.67, SD = 0.65,
118 range 0-5) with the UP treatment. The satisfaction variable can be related with the construct
119 number 1 of TFA model "Affective Attitude" In the case of the therapists, Thompson-
120 Brenner et al[25] aimed to study treatment fidelity in therapists who applied the UP in group
121 format to patients residing in specialized eating-disorder-treatment centers. The results
122 showed adequate to good fidelity to the treatment by the therapist. Despite this data is
123 provided for an UP certified supervisor and not directly provided by the therapists, we can
124 consider that UP fidelity can be related with constructs number 4 "Intervention Coherence",
125 6 "Perceived effectiveness" and 7 "self-efficacy" of the TFA model. However, to date,
126 acceptability from a broader point of view and specifically from the perspective of public
127 mental healthcare professionals (MHCPs) delivering the UP in group format has not been
128 explored.

129 Thus, the aim of this study is to explore MHCPs acceptability and opinion of
130 delivering the UP intervention in a group format, within the Spanish Public Mental Health

131 System, using the TFA and adding two more variables, general acceptability (acceptance to
132 apply the treatment in general) and the intention to use the UP in the future (intention to keep
133 using the treatment). These two additional variables will help us to understand from a broader
134 perspective the real possibilities of disseminating the UP to public mental health units in
135 Spain. We hypothesize that, consistent with the outcomes provided by patients, the UP will
136 be highly accepted by MHCPs, and we expect to find high expectations of intention to use it
137 in the future. Finally, we hope to collect more qualitative information through a SWOT
138 (Strengths, Weaknesses, Opportunities, Threats) analysis, the therapists' opinions to
139 determine the most advantageous aspects of this intervention, and its weaknesses and aspects
140 to be improved.

141 **Method**

142 **Participants**

143 Thirty-three mental healthcare professionals (MHCPs; clinical psychologists,
144 psychology residents, and psychiatrists) working within the Spanish Public Mental Health
145 System participated in this study. The participants were, on average, 42.66 years of age
146 (*SD*=11.88, range 26 to 62), and 81.8% of them (*n*=27) were women. They were grouped
147 into MHCPs without previous experience in delivering the UP (*n*=14) and MHCPs with
148 experience in delivering the UP (*n*=19). The remaining sociodemographic characteristics of
149 the sample can be found in Table 1.

150 -Insert Table 1 about here-

151 **Measures**

152 *Sociodemographic data*. The information collected, in addition to age and sex,
153 included questions about the current job (specialist in clinical psychology, psychology

154 resident, psychiatrist), years of professional experience in the context of public mental health,
155 number of hours of training received in the UP, and whether they have had experience
156 delivering the UP (as therapists or co-therapists).

157 *Acceptability and intention-to-use survey.* This questionnaire was created ad hoc for
158 this study and consists of nine items, seven of them based on the TFA model[19] and two more
159 items reflecting general acceptability and intention to use the UP in the future. The TFA
160 questions and/or statements were: (1) Affective attitude:"*Do you think you will like delivering*
161 *the UP treatment?";* (2) Burden:"*How much effort will it take to deliver the UP treatment?";*
162 (3) Perceived effectiveness:"*Do you think that the UP is likely to help patients to regulate*
163 *their emotions?";* (4) Ethicality:"*There are moral or ethical consequences to delivering the*
164 *UP treatment";* (5) Intervention coherence:"*It makes sense to me how UP treatment will*
165 *result in improvements in patients' regulating their own emotions"*;(6) Opportunity
166 costs:"*Delivering the UP treatment will interfere with my other priorities";* (7) Self-
167 efficacy:"*How confident do you feel about delivering the UP treatment?."* The two
168 additional questions were: (8) General acceptability:"*How acceptable is it to deliver the UP*
169 *treatment?"*; (9) Intention to use the UP in the future:"*To what extent do you think that you*
170 *would use this treatment in the future with your patients diagnosed with emotional*
171 *disorders?"* The answers were rated on a 5-point Likert scale ranging from 1 (according to
172 the question: *Strongly disagree/ No effort at all/ Strongly dislike/ Very unfair/ Very*
173 *unconfident or completely unacceptable)* to 5 (*Strongly agree/ Huge effort/ Strongly like/*
174 *Very fair/ Very confident/ Completely acceptable*).

175 *SWOT questionnaire*. This questionnaire consists of four open questions to assess the
176 strengths, weaknesses, opportunities, and threats related to the UP and its use in the Spanish
177 public mental health system.

Procedure

This study is being developed in the context of a multicenter randomized clinical trial that we are carrying out in Spain intending to analyze the efficacy and effectiveness of the UP applied in group format in the public mental health system[26]. MHCPs who were interested in collaborating in the trial were invited to complete a 20-hours training UP workshop before their participation. After the training, all MHCPs were invited to voluntarily complete an online anonymous survey with questions regarding the acceptability and intention to use the UP in the future (9 questions). Six months later, those MHCPs who had some experience delivering the UP in group format (as a therapist or as co-therapist), were invited again to complete the SWOT questionnaire through an online link. The decision of doing a SWOT analysis[27] was based on the fact that this approach has proven to be effective in mapping the general picture of a particular field[28]. SWOT analysis allows researchers to identify the resources, limitations, possibilities and risks of the particular object of study in order to find the optimal point between the internal strengths and weakness and the environmental trends (opportunities and threats) and also helps to formulate strategies and action plans based on the results of the assessment[29,30]. This analysis is especially useful for evaluating public and social policies and has been widely used to analyze health systems[31].

This research was conducted with the approval of the ethics committee of all the collaborating centers, and all participants signed informed consent before participation. No identifying information was collected, and the data were analyzed by independent research team members who had not participated in the MHCPs' training in order not to bias the results.

Data analysis

201 The quantitative analyses were carried out using the statistical package IBM SPSS
202 Statistics version 22.0 for Windows[32]. The qualitative data were analyzed following an
203 analytical framework based on the SWOT analysis[27].Through this analysis, it is possible to
204 obtain information that cannot be collected through the quantitative information and, above
205 all, in the public health context, it can be a powerful tool that facilitates the discussion, for
206 example, about the evaluation of the negative effects in psychotherapy[28].

207 Firstly, the sociodemographic characteristics of the sample were analyzed. Next, a
208 Kolmogorov-Smirnov test was performed to assess whether the sample followed a normal
209 distribution. Then, the means and standard deviation of the scores obtained were analyzed
210 for acceptability and intention-to-use responses. Next, Spearman's rho tests were conducted
211 to analyze whether there was a relationship between the sociodemographic variables and the
212 acceptability and intention-to-use scores in MHCPs. The same analyses were performed to
213 compare the scores of the two groups of MHCPs (with experience and without experience).
214 The mean difference analysis between the two groups was conducted through the Mann-
215 Whitney U-test. Also, correlations were calculated between the variables that are included
216 in the TFA, to evaluate the relationship between them in both groups of MHCPs.

217 Finally, text analyses were carried out using qualitative analysis on the responses
218 obtained through the SWOT questionnaire. These analyses were carried out through the
219 statistical program for qualitative analysis MAXQDA[33].

220 First, a member of the research team, unrelated to the MHCPs, supervised that all
221 responses introduced in the survey were correctly located into the corresponding SWOT
222 domains. Second, the texts corresponding to each of the SWOT domains were entered into
223 the MAXQDA program to carry out the text analysis. This analysis[34] consisted of generating
224 a system of codes, grouping the responses of the MHCPs that referred to the same ideas or

225 highlighting the main ideas. For example, one of the MHPCs mentioned as a strength *"... can be applied to various group diagnoses"* and another mentioned *"The transdiagnostic character of the intervention enriches it"* both phrases were assigned to the *"transdiagnostic nature"* code since that is the idea that could be extracted from both sentences. Another example was *"Its format and structure make it very efficient"* or *"It is easy to apply"* both sentences were assigned to the *"effectiveness"* code. This inductive process was repeated with each answer of the MHCPs, and once all the sentences were assigned to the codes, they were grouped in higher categories, whenever possible, in order to facilitate their analysis. Following the example above, both codes were grouped in the category *"transdiagnostic effectiveness"*. Two different members of the research team conducted independently this second process.

236 The MAXQDA program extracted twenty-five categories that included the main ideas given by the MHCPs. The results of the general coding system and the creation of the categories were discussed by the members of the research team.

Results

Sociodemographic characteristics of the sample

241 Firstly, the Kolmogorov-Smirnov test for normality showed that the sample did not follow a normal distribution ($p<.05$), so the analyses were performed with non-parametric tests. The Mann-Whitney *U*-test showed no significant differences for sociodemographic data between MHCPs with no experience in delivering the UP and MHCPs with experience ($p>.05$), except for the number of hours of UP training ($Z=-2.28$, $p=.023$), which was higher in the second one.

247

248 *Scores of the MHCPs in the TFA model, general acceptability and intention to use in the*
249 *future*

250 The means and standard deviation from the MHCPs and the two subsamples can be
251 seen in Table 2. In general, the results showed high Affective attitude (*M*=4.58, *SD*=.50),
252 Perceived Effectiveness (*M*=4.21, *SD*=.48), Intervention coherence (*M*=4.45, *SD*=.56), Self-
253 efficacy (*M*=3.88, *SD*=.89), General Acceptability (*M*=4.30, *SD*=.68, range=3-5) and
254 Intention to use (*M*=4.54, *SD*=.56, range=3-5) and low Burden (*M*=2.85, *SD*=1.03),
255 Ethicality (*M*=1.64, *SD*=1.11), and Opportunity costs (*M*=2.00, *SD*=1.03).

256 When comparing scores between groups, the results showed statistically significant
257 differences in Affective Attitude (*Z*=-2.85, *p*=.004) and Self-Efficacy (*Z*=-2.75, *p*=.014), in
258 favor of the MHCPs group with experience in delivering the UP. No statistically significant
259 differences were found in the remaining variables.

260 -Insert Table 2 about here-

261 *Relationships between TFA, general acceptability, and intention to use*

262 The results of the Spearman's rho tests showed a moderate positive relationship
263 between the different constructs of the TFA, specifically, between the Affective Attitude and
264 Perceived Effectiveness (r_s=.51, *p*=.002) and Self-Efficacy (r_s=.46, *p*=.007). A moderate
265 positive relationship was obtained between Burden and Opportunity Costs (r_s=.53, *p*=.001),
266 also between Perceived Effectiveness and Self-Efficacy (r_s=.37, *p*=.031), and Intervention
267 Coherence (r_s=.48, *p*=.005). Ethicality and Opportunity Costs also showed a moderate
268 positive relationship (r_s =.54, *p*=.001). The rho test showed a moderate positive relationship
269 between General Acceptability and the constructs: Affective Attitude (r_s=.59, *p*<.001) and
270 Intention to Use in the future (r_s=.55, *p*=.001). Finally, the results showed a positive medium

271 relationship between intention to use and the following TFA constructs: Affective Attitude
272 (r_s=.51, p=.002), Intervention Coherence (r_s=.37, p=.033) and Self-Efficacy (r_s=.36, p=.042).

273 The different ways in which the variables of the TFA model and general acceptability
274 and intention to use in the future are correlated can be seen graphically in Figure 1.

275 -Insert figure 1 about here-

276 When analyzing the correlations in the group of MHCPs with no experience in
277 delivering the UP, the results showed a moderate positive correlation between Ethically and
278 Opportunity Costs (r_s=.65, p=.011) and a high positive correlation between Intervention
279 Coherence and General Acceptability (r_s=.70, p=.005). We also found a moderate negative
280 correlation between Opportunity Costs and Self-Efficacy (r_s=-.64, p=.014).

281 Regarding the group of MHCPs with experience, the results showed a moderate
282 positive correlation between age and Intention to Use (r_s=.59, p=.008) and also between years
283 of work and: Affective Attitude (r_s=.52, p=.022) and Intention to Use (r_s=.54, p=.016). We
284 also found a moderate to high positive correlation between Affective Attitude and Perceived
285 Effectiveness (r_s=.49, p=.034), General Acceptability (r_s=.59, p=.008) and Intention to Use
286 (r_s=.71, p=.001). Moderate positive correlations between Burden and Opportunity Costs
287 (r_s=.59, p=.008), between Perceived Effectiveness and Intervention Coherence (r_s=.60,
288 p=.007), and between General Acceptability and Intention to Use (r_s=.69, p=.001). The
289 correlation results can be seen in Table 3.

290 -Insert Table 3 about here-

291 *Qualitative results through SWOT analysis*

292 The results of the SWOT analysis can be found in table 4. When analyzing the results
293 obtained by MHCPs with experience in delivering the UP, most of them mentioned as its

294 main strength the transdiagnostic effectiveness (*n*=10): "*The transdiagnostic character of the*
295 *intervention enriches it*". Regarding the weaknesses, most clinicians considered the
296 difficulties inherent in the group format (*n*=6):"*Setting up group schedules is always*
297 *difficult*". In terms of opportunities, most of the clinicians mentioned adapting the material
298 and the number of sessions according to the characteristics of the patient as an opportunity
299 (*n*=8): "*Adapting it to the participants (people who do not like reading, educational levels;*
300 *reducing some text and replacing it with images*)". Finally, concerning threats, most
301 mentioned the lack of resources (human and material) (*n*=7) with phrases such as "*lack of*
302 *support from human resources (professional collaborators, lack of psychologists*).

303 -Insert Table 4 about here-

304 **Discussion**

305 The aim of this study was to explore MHCPs acceptability, intention to use in the
306 future, and opinion of delivering the UP intervention in a group format, within the Spanish
307 Public Mental Health System.

308 We hypothesized that the UP would be widely accepted and would score highly in
309 every facet of the TFA. Overall, the first hypothesis was supported. Specifically, the results
310 of this research showed high general acceptability by MHCPs, with an average score of 4.30
311 out of 5, and it was high both in professionals who had received training in the UP but who
312 had not yet applied it, and in professionals with experience in delivering the UP. The same
313 applies to the perceived effectiveness and coherence of the intervention. As we can see, the
314 implementation of the knowledge acquired further reinforces the idea that the UP is a highly
315 valid and accepted intervention, and once it has been applied, practically all professionals
316 assure that they would use it again in the future.

317 The results of this study have shown that, in general, there is a positive relationship
318 between the affective attitude, intervention coherence, self-efficacy, general acceptability,
319 and the intention to use the UP in the future. Therefore, these aspects must be evaluated and
320 considered to achieve a correct implementation. Furthermore, as we have seen, the affective
321 attitude and self-efficacy were greater in MHCPs with experience in using the UP, which
322 reflects the importance of not only offering theoretical training in evidence-based treatments
323 but of putting this knowledge into practice so that, once it has been seen how it works in a
324 real context, it is more likely to be used in the future.

325 Also, the results of this research have shown that, for those MHCPs with no
326 experience in delivering the UP, high intervention coherence is related to high general
327 acceptance. In this sense, protocolized and structured treatments such as the UP can facilitate
328 its acceptance. In addition, it is important to note that if a treatment is thought to lead to
329 losing other opportunities (e.g., thinking that other materials or techniques outside the ones
330 provided by the UP could be beneficial), this will affect clinicians' self-efficacy, or if it is
331 considered to have ethical or moral consequences, this will negatively affect the clinician's
332 assessment of the intervention. In order to reduce the influence of these two variables, we
333 must consider two recommendations for UP trainers. The first one is the need to highlight
334 the versatility and personalization of the UP. The UP allows therapists to adapt or to add as
335 many exercises or techniques as they deem necessary to train a specific emotion-regulation
336 strategy. An example is the study by de Ornelas et al[35], who included the problem-solving
337 technique to help patients in their relationships. The second one is the importance of
338 explaining the theoretical framework that justifies the modules and techniques that have been
339 incorporated into the UP and why it is considered that these modules will improve patients'
340 emotion-regulation and symptoms[24].

341 Regarding the MHCPs with experience in the application of UP, there was a
342 relationship between the intervention's coherence and its perceived effectiveness and also
343 between these variables' and a favorable attitude towards the UP. This favorable attitude is
344 related to the general acceptability and the intention to use the intervention in the future. The
345 fact that the therapists have a favorable attitude and widely accept the treatment they apply
346 will encourage them to use this treatment again in the future, enhancing its dissemination.
347 This is especially important if we consider that, in Europe, less than 10% of people with
348 mental disorders receive theoretically adequate treatment[36]. This is probably why the
349 dissemination of evidence-based psychological treatments is a goal of health system policies
350 and other agencies such as the National Institute for Health and Care Excellence (NICE)[37].

351 If we want to promote the dissemination of evidence-based psychological treatments,
352 it is necessary to train MHCPs[38], as proposed in the model for the dissemination called train-
353 the-trainer[39], which is especially important for therapists working in the public mental health
354 system. In this sense, training therapists in the UP reduces the costs and effort of having to
355 train and learn a different intervention for each ED[13].

356 The results of this study have shown that professionals with more years of work
357 experience show a better affective attitude and intention to use the UP in the future. This can
358 be an important result if we consider that these professionals have more expertise in
359 psychotherapy and have more knowledge about what therapeutic resources are usually
360 effective. Moreover, this result also reflects the importance of practice, it is likely that after
361 using the UP, these professionals observed their ability to apply the intervention and the
362 benefits obtained by the patients, enhancing their favorable attitude towards the treatment
363 and towards using it in the future.

One of the strengths of this study is its therapist-opinion orientation because knowing the opinions of MHCPs about the interventions they apply can help improve them. Therefore, collaboration between researchers and clinicians should be encouraged by creating a practice-oriented system[40]. From this approach, the SWOT analysis showed that, according to the MHCPs, the UP delivered in group format has a series of strengths mainly related to its transdiagnostic nature and cost-effectiveness. These results are in line with previous studies that underscore the benefits of the UP: it facilitates the organization of groups with an ED diagnosis, allowing more patients to be treated at the same time and, as a consequence, it reduces the pressure on the public mental health system[16]. These arguments are in line with the recommendations of the 2030 agenda for sustainable development[1].

The MHCPs also identified great opportunities offered by the UP by adapting it when necessary. This statement makes sense because the UP is a versatile intervention structured into different modules, which facilitates its personalization to different patients, contexts, or disorders. For example, the UP has been delivered by increasing or reducing the number of sessions[24], it has been adapted to treat EDs in a sample of female victims of intrafamilial violence in a social service context[41], and it has been used for the treatment of patients with personality disorders or traits[42,43].

Regarding weaknesses and threats, the MHCPs identified some negative consequences, which were generally been due to the application format and focused on the amount of resources required to carry out intervention groups (greater availability of human and material resources). As mentioned, clinicians working in the Spanish Public Mental Health System have high assistance pressure due to the long waiting lists[6], and conducting group therapies does not necessarily imply having more time to prepare the sessions or the possibility of having a co-therapist. Thus, group therapy sometimes implies an overburden for clinicians. Therefore, the lack of human and economic resources in public health settings

389 is a barrier to applying a cost-effective group intervention. This underlines the fact that public
390 and social policies must be urged to strengthen the Mental Health System, and this requires
391 greater investment in this sector.

392 Concerning the limitations of the study, on the one hand, the sample of participants
393 was obtained from among the collaborators in our ongoing trial[26] , so their responses may be
394 biased towards a favorable attitude towards the UP. The same applies to the higher number
395 of psychologists than other mental health professionals such us psychiatrist. Also, the
396 reduced size of the sample has limited the proposed analyses and the generalization of the
397 results, which must be treated with caution. We also have to consider that the UP is a recent
398 psychological intervention that is growing in interest but there are still few therapists who
399 have heard about it, or have received training or a certification course, or have had experience
400 applying the UP in group format in public health settings in Spain. On the other hand, this
401 study took place in public mental health settings, so the conclusions might not be
402 generalizable to other contexts such as community or social services, but precisely, having
403 been carried out in a naturalistic context is one of the strengths of this study.

404 In sum, findings indicate high acceptability of and intention to use the UP in the future
405 by MHCPs working within the Spanish Public Mental Health System, and also identified
406 areas for improvements. In order to enhance the dissemination and implementation of the
407 UP, it is essential to consider MHCPs' perceptions and to be open to their suggestions for
408 improving and enhancing the treatment outcomes.

409

410 **Acknowledgments**

411 We would like to thank all collaborating centers, and all the healthcare professionals
412 who made this study possible.

413 **Contributors**

414 All persons who met authorship criteria are listed as authors and all authors
415 contributed to and approved the final manuscript.

416 **Funding**

417 Funding for the study was provided by the PI17/00320 project integrated in Plan
418 Estatal de I+D+I 2013-2016, and it was co-funded by the "ISCIII-Subdirección General de
419 Evaluación y Fomento de la investigación del Fondo Europeo de Desarrollo Regional
420 (FEDER). Otra manera de hacer Europa." The research team S31_20D has also received
421 funds by the Gobierno de Aragón and FEDER 2014-2020 "Construyendo Europa desde
422 Aragón."

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