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Therapeutic alliance in a stepped digital psychosocial intervention for breast cancer patients: findings from a multicentre randomised controlled trial

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Background

Action mechanisms of therapeutic alliance in stepped and digital interventions remain unclear.

Aims

(a) To compare the development of therapeutic alliance between psychosocial treatment as usual (PTAU) and a stepped digital intervention designed to prevent distress in cancer patients; (b) to analyse the level of agreement between patients' and therapists' therapeutic alliance ratings; and (c) to explore variables associated with therapeutic alliance in the digital intervention.

Method

A multicentre randomised controlled trial with 184 newly diagnosed breast cancer women was conducted. Patients were assigned to digital intervention or PTAU. Therapeutic alliance was assessed at 3, 6 and 12 months after inclusion using the working alliance inventory for patients and therapists. Age, usability (system usability scale), satisfaction (visual analogue scale), type and amount of patient–therapist communication were analysed as associated variables.

Results

Patients and therapists established high therapeutic alliance in the digital intervention, although significantly lower compared with PTAU. The development of patients' therapeutic alliance did not differ between interventions, unlike that of the therapists. No agreement was found between patients' and therapists' therapeutic alliance ratings. Patients' therapeutic alliance was associated with usability and satisfaction with app, whereas therapists' therapeutic alliance was associated with satisfaction with monitoring platform.

Conclusions

A stepped digital intervention for cancer patients could develop and maintain strong therapeutic alliance. Neither the type nor amount of communication affected patients' therapeutic alliance, suggesting that flexible and available digital communication fosters a sense of care and connection. The association between usability and satisfaction with digital tools highlights their importance as key therapeutic alliance components in digital settings.

Keywords

Cancer survivor; mHealth; psycho-oncology; stepped-care; therapeutic alliance.

Background

The study of how the digital environment impacts on the development of the therapeutic alliance was established in 2018 as one of the top ten research priorities for mental digital healthcare by the James Lind Alliance, an initiative of the National Institute of Health Research of the United Kingdom.[1] Defined by Bordin,[2] therapeutic alliance encompasses the collaborative relationship and adjustment between patient and therapist. It is composed of three components: (a) agreement on intervention aims; (b) agreement on tasks carried out during the psychotherapeutic process; and (c) the bond formed by the affective ambience. Research studies have consistently shown that the strength of therapeutic alliance not only predicts in-person psychotherapy outcomes,[3] including cancer patients,[4] but also improves other key factors, such as treatment adherence.[5] However, its role and significance in new, upcoming psychosocial care approaches are not yet well studied. This is particularly true in the context of digital and stepped care interventions,[1,6] where the dynamics of patient–therapist interactions may differ significantly from in-person settings.

Stepped care interventions involve tailoring interventions based on patients' clinical complexity, with increasing intensity as needed. Several research teams have explored them to address emotional distress among diverse cancer populations, with varying effectiveness: some studies have shown significant reductions in distress,[7] while others found this effect in patients with higher baseline distress.[8] In contrast, some researchers reported no significant changes in this outcome after the intervention.[9] Another element that may impact therapeutic alliance and that is being used to improve access to psychosocial care in cancer is the use of eHealth technologies.[10] However, studies comparing digital interventions with conventional ones have produced mixed results; some report similar effect sizes between digital and in-person interventions,[11] whereas others observed smaller effects in digital interventions.[12] Furthermore, the integration of eHealth into stepped interventions is a relatively recent development in healthcare, with limited empirical evidence on the effectiveness of fully digital

stepped interventions in cancer populations.[13] For example, Hauffman et al[13] evaluated a digital stepped psychosocial intervention in different cancer populations, resulting in heterogeneous psychological outcomes: reductions in depressive symptoms were observed, but no effects were found on anxiety, post-traumatic stress, or quality of life.

Disparities in the effectiveness of digital interventions may be potentially explained due to the lack of theoretical and empirical frameworks that define how different action mechanisms correlate with effectiveness outcomes in digital settings.[14] Those inconsistent results on their effectiveness highlight the importance of studying therapeutic process factors,[12] particularly those that differ the most from in-person interventions, such as therapeutic alliance.[15,16] By understanding how therapeutic alliance works in digital settings, we can better address the factors contributing to inconsistent effectiveness and improve the design of eHealth interventions.

Current knowledge about therapeutic alliance in digital settings

Over the past decade, there has been increasing interest in exploring therapeutic alliance across various digital intervention formats.[1] According to several studies, patients report high levels of therapeutic alliance, regardless of patient sociodemographic characteristics (e.g. age, gender, education level), diagnosis, communication type (i.e. synchronous or asynchronous communication) or intervention format (e.g. video-consultations, text messages).[4,10,17,18] However, recent studies involving cancer patients have found both text messages (i.e. asynchronous communication)[19] and video consultations[20] to hinder the development of a fluid dialogue, negatively affecting therapeutic alliance. In the same line, therapists tend to report lower levels of therapeutic alliance compared with patients, with some expressing concerns about the negative impact of digital tools on their own therapeutic alliance.[16–18,21]

Other authors had focused on how different intervention formats may influence digital therapeutic alliance diversely. For instance, video consultations, characterised by synchronous communication of verbal and non-verbal information, are considered the most similar to in-person interventions, and may establish stronger therapeutic alliance compared with other digital interventions.[15,17,22]

Moreover, previous studies suggested that the proficiency or ease of use of eHealth tools can moderate therapeutic alliance perception of both patients and therapists.[23,24] High usability can enhance user experience and satisfaction, fostering seamless interactions, greater involvement in the therapeutic process, and ultimately leading to a higher therapeutic alliance.[17,24,25] In turn, patients' age could be related to tool use[26] affecting those variables.

Although digital interventions generally show high levels of therapeutic alliance, research in this area remains limited and results are not entirely conclusive, particularly in oncology patients or from therapists' perspective.[19,23,27] Additionally, there is a lack of evidence on therapeutic alliance in digital stepped interventions, where therapists only interact with patients on detecting psychosocial needs and may need to adapt communication approaches based on the level of care required.

Rationale, aims and hypotheses

This study presents further analysis of a broader multicentre randomised controlled trial (RCT) which assessed the effectiveness of ICOnnecta't, a stepped digital psychosocial intervention designed to prevent emotional distress, to promote adaptation in breast cancer patients, and to facilitate communication between patients and healthcare providers.[28] A recent preliminary study has shown its feasibility.[26] In this secondary analysis we aim to: (a) compare the development of therapeutic alliance between ICOnnecta't and psychosocial treatment as usual (PTAU) from the perspectives of breast cancer patients and their therapists; (b) analyse the level of agreement between patients' and therapists' therapeutic alliance ratings for both treatment conditions; (c) explore potential variables associated with therapeutic alliance during ICOnnecta't intervention, in particular age, platform usability and satisfaction, and type and amount of patient–therapist communication. We hypothesised that: (a) there will not be significant differences in the development of therapeutic alliance between ICOnnecta't and PTAU from patients' and therapists' perspectives; (b) therapists will report lower levels of therapeutic alliance compared with patients in both interventions; (c) younger age, high usability and satisfaction, greater communication and video consultations will be positively associated with therapeutic alliance scores for both patients and therapists.

Method

Design

This is a multicentre RCT with two parallel groups, ICOnnecta't versus PTAU, with a 1:1 allocation. The study design contains two treatment conditions and four assessments (2×4 factors) during a 12-month intervention period. Extensive methodological and intervention protocols were previously published.[26,28]

All procedures performed in this study involving human participants were conducted in accordance with the ethical standards of the institutional and research committee and with the Helsinki Declaration of 1975, as revised in 2013. The protocol was approved by the Clinical Research Ethics Committee of the participant institutions on 7 November 2019 (PR289/19). It was submitted to ClinicalTrials.gov on 24 April 2020 (NCT04372459).

Participants

Participants were recruited from two public health centres located in the province of Barcelona (Spain), namely a specialised cancer institute (Institut Català d'Oncologia L'Hospitalet) and a general hospital's oncology service (Hospital de la Santa Creu i Sant Pau). Inclusion criteria were: (a) adult women (≥18 years); (b) diagnosed with a first episode of breast cancer within the previous 8 weeks; (c) who had a mobile phone with internet access and user-level skills; and (d) were fluent in Spanish (both reading and writing). Patients with major depressive disorder, psychosis, substance abuse, autolytic ideation or cognitive impairments (e.g. neurological disorders) were excluded and referred to more specialised care.

Group conditions and therapists

Experimental group ICOnnecta't

ICOnnecta't is a stepped digital intervention comprising four care levels staggered by psychosocial complexity (see Fig. 1): (a) psychosocial screening and monitoring through a mobile app; (b) guided psychoeducation through a Moodle Campus integrated within the app;[29] (c) supervised peer-support community app; and (d) group psychotherapy treatment through multi-video consultation based on the Positive Group Psychotherapy Program in Cancer.[30] By systematically monitoring the emotional distress in the first level, the patient's psychosocial status can be measured to decide if they need to continue to a more intensive and complex level of care.

Throughout the entire intervention period, the patient is consistently accompanied by the same therapist. The app enables asynchronous communication via text messages during the 12-month

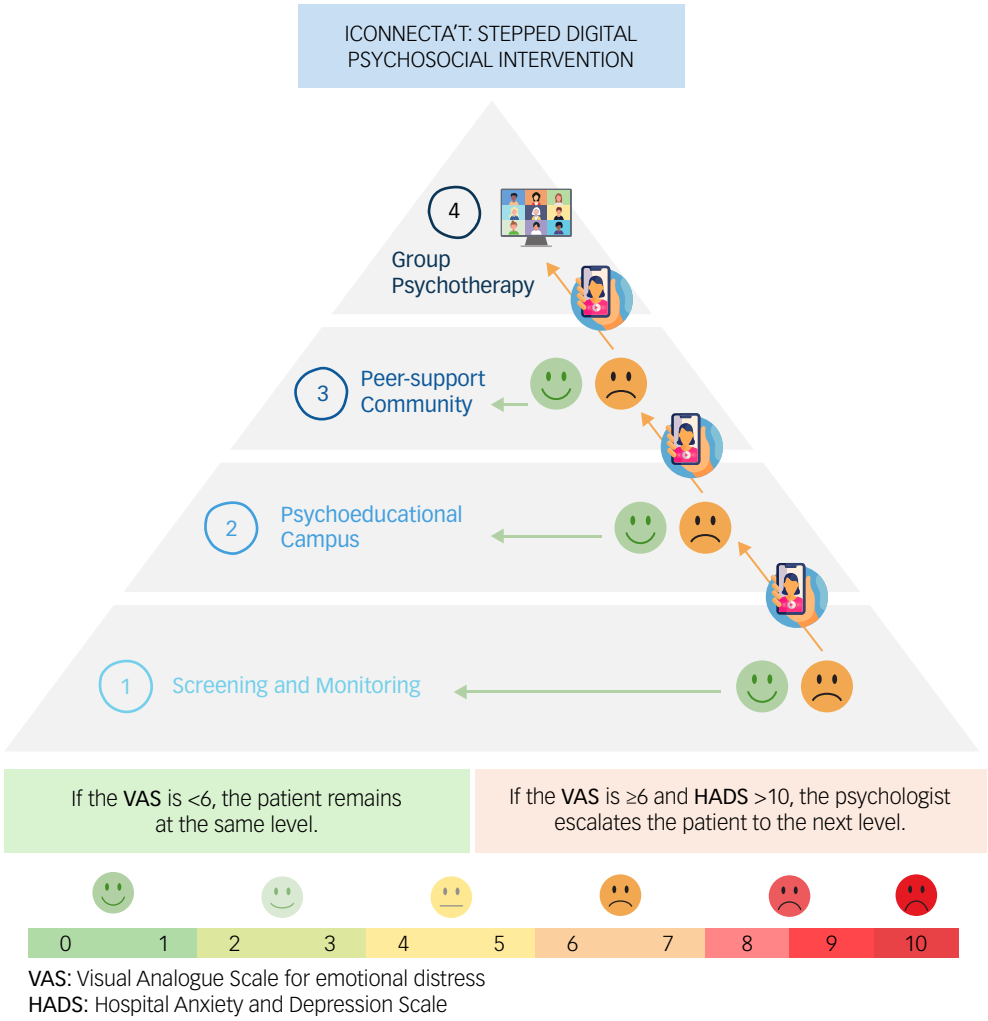

Fig. 1 Stepped digital psychosocial intervention ICOnnecta't: intervention levels and stepped protocol. Adapted from a previous ICOnnecta't protocol with permission from the authors and the publisher.[29]

intervention period. Additionally, the progression from one level to another is often preceded by a synchronous video consultation; however, there are patients who reject video consultations and prefer to do the entire stepped intervention through messages. These interactions and accompaniment are intended to provide ongoing support throughout the patient's cancer journey.

Control group psychosocial treatment as usual (PTAU)

Participants in the control group received a standard in-person psychosocial treatment for cancer patients to prevent emotional distress and facilitate the illness adaptation during the first year after diagnosis. To homogenise criteria, patients received eight individual 45–60-min sessions during the 12-month intervention period, focusing on emotional support and psychoeducation.[28]

Therapists

The study involved six postgraduate psychologists with specific psycho-oncology training (i.e. master's degree in psycho-oncology and health or clinical psychology) and previous experience in psycho-oncological interventions. Four of them participated in both group conditions, and two exclusively in the experimental group. Several training and supervision sessions were conducted throughout the implementation of the study to ensure adherence to the intervention protocol.

Procedure

Participants were recruited from the breast cancer units of the participating hospitals from 21 June 2021 to 30 June 2022. Eligible patients were invited to participate. Patients who expressed interest were scheduled to meet with a psychologist of the research team to discuss the study details, confirm eligibility (i.e. inclusion and exclusion criteria), provide and sign informed consent, and randomly assign them to one intervention group. The randomisation was conducted by an independent researcher using a list of randomly generated numbers via IBM SPSS.27.[32] The psychologist in charge of the recruitment interview was responsible for communicating the assigned treatment.

The app was downloaded onto experimental group patients' smartphones, and they were provided with both oral, written and video instructions on how to use it. In contrast, a first in-person visit was arranged between the control group patients and a psychologist of the team. Treatment was administered for 12 months, and assessments were conducted using online instruments administered by Qualtrics[XM][33] at study baseline (T1), and at 3 (T2), 6 (T3) and 12 (T4) months after the inclusion.

Measures

Primary outcome

Therapeutic alliance. The working alliance inventory short form (WAI-S) is a self-report questionnaire designed to measure the

therapeutic alliance between therapist and patient.[34] Both the patient (WAI-S-P) and therapist (WAI-S-T) versions consist of 12 items, with four items measuring each of the three components of the therapeutic alliance described by Bordin:[2] (a) agreement regarding intervention' goals; (b) agreement on the tasks; and (c) the affective bond between therapist and patient. Although there are several instruments to measure therapeutic alliance with good psychometric properties, this one was designed to assess the therapeutic alliance components across various therapy modalities.[35] That is why it has been widely used in digital interventions with cancer patients.[4,27] The validity of this instrument has been established in the Spanish population,[34] showing excellent reliability for both forms, WAI-S-P ($\alpha = 0.93$) and WAI-S-T ($\alpha = 0.94$). The subscales also demonstrated high reliability. Total scores range from 12 to 84, while subscales range from 4 to 28, with higher scores indicating stronger therapeutic alliance. Consistent with previous research,[4,27] the present study utilised the same instrument in both treatment conditions, without modifying any item, to ensure comparability of therapeutic alliance measures. This approach was adopted due to the lack of consensus and specific scales for evaluating digital therapeutic alliance.[36] Therapeutic alliance assessments were conducted on patients and therapists from both treatment conditions at T2, T3 and T4.

Secondary outcomes

Usability. The system usability scale (SUS) was used to assess the ease to use the digital platform among patients and therapists at T3 for the experimental group. It is a 10-item questionnaire designed to measure the perceived usability of a system or product.[37] The SUS has been widely used and validated in various domains, including healthcare and technology.[38] It has shown good reliability ($\alpha = 0.70–0.97$). The scores range from 0 to 100, with higher scores indicating better usability. Researchers have suggested that a score above 68 is above average, while a score above 80 is excellent.[39]

Satisfaction. Satisfaction with the app was assessed at T3 of experimental group with a 0–10 visual analogue scale (VAS) (i.e. How satisfied are you with the ICOnnecta't app, where 0 is completely unsatisfied and 10 is completely satisfied?). Therapists scored a similar VAS about the satisfaction with the professional ICOnnecta't platform. The literature does not provide a clear cut-off, so we considered scores ≥ 5 as indicating some level of satisfaction, while scores ≥ 8 were considered high.[26]

Communication type. Experimental group patients' communications were categorised based on the intervention format employed: (a) unanswered asynchronous communication, for patients who received and read the therapist text messages but never answered; (b) asynchronous communication, for patients who interacted with therapist through text messages; and (c) mixed communication, for patients who interacted through text messages and video consultations.

Communication amount. The number of text messages exchanged between therapist and patient, and the number of video consultations conducted were added together to analyse the interaction quantity between both.

Data analysis

Categorical variables were presented as the number of cases and percentages. Continuous variables were presented as means and s.d. or medians and interquartile range, depending on whether the distribution was normal or non-normal. Normality was assessed through visual inspection of quantile–quantile plots, histograms and s.d. from normality plots.

Multiple imputation by chained equations was applied to account for missing data in measures of therapeutic alliance. The assumption that unobserved values were missing at random was deemed to be appropriate because we could not find any pattern among the missing values.[40] Fifty iterations of imputation were performed.

Logistic regressions were conducted to compare attrition between arms, assessing both adherence (i.e. participants who did not drop out of treatment) and retention (i.e. participants who completed assessments at all follow-ups). Then, modified intention-to-treat analyses were conducted, excluding 15 participants without any observation in WAI-S-P or WAI-S-T.

Moving on the study objectives, to analyse the growth curve of the therapeutic alliance over the treatment period and compare it between arms separately for patients and therapists (i.e. aim 1), we calculated linear mixed-effect models (LMMs) with patient clustering between T2 and T4 of the WAI-S-P and WAI-S-T total and subscales scores.

Second, to study the agreement between patients and therapists on therapeutic alliance scores in each assessment time point and treatment group (i.e. aim 2), *t*-test and Cohen's *d* for paired data were calculated. Cohen's *d* values less than 0.50 indicate small effect; between 0.50 and 0.80 indicate medium effect; and above 0.80 are considered large.[41] The intraclass correlation coefficient (ICC) was also estimated, because it provides a single measure of agreement that captures both the correlation and the level of conformity between ratings. ICC values lower than 0.70 show weak concordance.[42]

Finally, to explore factors associated with both WAI-S-P and WAI-S-T at T4 (i.e. the end of intervention, when the therapeutic alliance is considered established) in the experimental group (i.e. aim 3), independent univariate linear regressions were estimated for each variable. Then, a multivariate model was performed using forward and backward steps. In backward elimination, variables with the highest *P* values above the significance level are removed sequentially, refitting the model each time until all remaining predictors are statistically significant. In forward selection, starting with a minimal model with the factors selected in backward elimination, variables with the smallest *P* values below the significance level are added one by one, repeating the process until no additional variables meet the significance criterion.

For all outcomes, 95% confidence intervals (CI) were calculated. The significance threshold was set at a two-sided alpha value of 0.05, unless otherwise indicated. All statistical analyses were conducted with R software, version 4.3.3.[43]

Results

Participants characteristics

Out of the 383 referred patients, 184 agreed to participate in the study. This indicated an acceptance rate of 48.04%. Demographic and clinical baseline characteristics are summarised in Table 1.

Analyses indicated no statistically significant differences in attrition between arms for participant adherence to the intervention (coefficient [95% CI] = 0.654 [0.787–4.697], $P = 0.151$) or retention at T1 (coefficient [95% CI] = −0.143 [0.311–2.417], $P = 0.785$), at T2 (coefficient [95% CI] = 0.511 [0.849–3.271], $P = 0.137$), at T3 (coefficient [95% CI] = 0.423 [0.792–2.945], $P = 0.207$), and at T4 (coefficient [95% CI] = 0.168 [0.631–2.218], $P = 0.600$). Fifteen patients were excluded from the final analysis due to the absence of WAI-S-P or WAI-S-T observations, leaving a final sample of

Table 1 Demographic and clinical characteristics of intervention groups ($N = 184$)

	ICOnnecta't ($n = 100$)	PTAU ($n = 84$)
Mean age (s.d.)	52.6 (10.5)	54.8 (9.37)
Marital status, *n* (%)		
Single	6 (6)	11 (13.1)
Married/partnered	74 (74)	56 (66.67)
Divorced/separated	13 (13)	11 (13.1)
Widowed	7 (7)	4 (4.76)
Unknown	0 (0)	2 (2.38)
Education, *n* (%)		
No studies	1 (1)	2 (2.38)
Primary	9 (9)	7 (8.33)
Secondary	15 (15)	11 (13.1)
Professional training	40 (40)	37 (44.05)
University degree	35 (35)	25 (29.76)
Unknown	0 (0)	2 (2.38)
Work status, *n* (%)		
Active	19 (19)	19 (22.62)
Unemployed without insurance	15 (15)	9 (10.71)
Unemployed with insurance	6 (6)	5 (5.95)
Work leave	47 (47)	41 (48.81)
Retired	13 (13)	8 (9.52)
Unknown	0 (0)	2 (2.38)
Cancer stage, *n* (%)		
0	4 (4)	10 (11.9)
I	38 (38)	30 (35.71)
II	36 (36)	31 (36.9)
III	16 (16)	8 (9.52)
IV	6 (6)	5 (5.95)

169 participants. Details of the participant flowchart are provided in Fig. 2.

Regarding therapists' characteristics, out of the six therapists, four were women. The median age was 32.33 years (s.d. = 9.89, range 26–52); and the median years of psycho-oncologist experience were 8.33 years (s.d. = 9.85, range 2–28).

Aim 1: development of therapeutic alliance

The initial LMM for both WAI-S-P and WAI-S-T and their subscales included the intercept, as well as time and group condition, as fixed effects. These data, along with the mean scores, are detailed in Table 2.

The analysis for WAI-S-P indicated statistically significant differences between interventions in total therapeutic alliance and its subscales, favouring PTAU. Regarding time, there were significant improvements for total, goals and tasks scores from T2 to T3, but not to T4, suggesting that therapeutic alliance increased in the first stages of treatment and then remained stable for both arms. In contrast, the bond subscale showed significant increase only from T2 to T4 because it registered a decrease at the end for both treatments.

The analysis for WAI-S-T also revealed significant differences between interventions in total scale and subscales, with higher scores in PTAU. Over time, there were significant improvements in total, goals, and tasks scores in both groups, whereas bond scores remained stable.

Later, the interaction between time and group was added in a subsequent model. This interaction was not significant for any of the WAI-S-P models, indicating that the development of therapeutic alliance and its components did not differ between ICOnnecta't and PTAU. However, it was significant for total WAI-S-T (coefficient [95% CI] = −2.91 [−5.53 to −0.29], $P = 0.030$), suggesting that therapeutic alliance varied between interventions, with greater development in PTAU.

Finally, an additional model was built adjusted for patients' age and therapists' experience. No significant changes were observed either in WAI-S-P (age: coefficient [95% CI] = 0.07 [−0.15 to 0.29], $P = 0.551$; experience: coefficient [95% CI] = −0.11 [−0.32 to 0.10], $P = 0.307$) or WAI-S-T (age: coefficient [95% CI] = −0.03 [−0.14 to 0.08], $P = 0.581$; experience: coefficient [95% CI] = −0.09 [−0.20 to −0.01], $P = 0.079$).

Aim 2: agreement between patients and therapists

Table 3 presents therapeutic alliance scores comparisons between patients and therapists. At T2 and T3 no significant differences were found for ICOnnecta't or PTAU, although significant differences were observed at T4 in both groups, with therapists reporting stronger therapeutic alliance. However, only one significant and positive ICC was found in therapeutic alliance scores of ICOnnecta't group at T3, although weak (for WAI-S subscales details, see Supplementary Table 1 available at https://doi.org/10.1192/bjo.2024.844).

Aim 3: variables associated with therapeutic alliance in ICOnnecta't intervention

Variables description

Usability and satisfaction. We had valid data on these instruments from 64 participants. The ICOnnecta't app received a mean patient satisfaction score of 7.64 (s.d. = 1.88). Among these participants, 35.94% ($n = 23$) expressed satisfaction with the platform, while 59.38% ($n = 38$) reported being very satisfied. The usability assessment, measured by the SUS, resulted in a mean score of 74.14 (s.d. = 16.14). The 59.38% ($n = 38$) of participants found that the platform was usable, while 39.06% ($n = 25$) considered it very usable. Regarding the professional platform, therapists' mean satisfaction level was 7.67 (s.d. = 0.82), and the usability was 85.42 (s.d. = 5.79).

Communication type. Ten patients (10.53%) did not establish any communication with their therapists; 15 (15.79%) received and read the therapist's messages but never answered (i.e. unanswered asynchronous communication); 39 patients (41.05%) interacted with their therapist just through messages (i.e. asynchronous communication); and 31 patients (32.63%) interacted through both messages and video-consultations (i.e. mixed communication).

Communication amount. Patients sent a mean of 7.71 messages (s.d. = 11.01, range 0–59), while they received 13.3 from their therapist (s.d. = 12.69, range 0–76). A mean of 1.08 video consultations were conducted per patient (s.d. = 2.68, range 0–16). The mean communication amount (i.e. sum of messages exchange and video consultations conducted) was 22.26 (s.d. = 25.58, range 0–151).

Association analysis

In the univariate regression model for patients, satisfaction (coefficient [95% CI] = 5.2 [2.9–7.5], $P < 0.001$) and usability (coefficient [95% CI] = 0.57 [0.29–0.85], $P < 0.001$) significantly explained the variance in WAI-S-P at T4. These two variables were the only ones selected in the multivariate model (R^2 adjusted = 0.287), indicating significant association with WAI-S-P (satisfaction: coefficient [95% CI] = 3.70 [1.15–6.26], $P = 0.005$; usability: coefficient [95% CI] = 0.37 [0.57–0.67], $P = 0.017$). Patients' age, communication type, and communication amount were not significant in explaining therapeutic alliance scores.

Finally, in the univariate regression model for therapists, satisfaction (coefficient [95% CI] = −7.1 [−10 to −3.8], $P < 0.001$), mixed communication (coefficient [95% CI] = 12 [1.9–22],

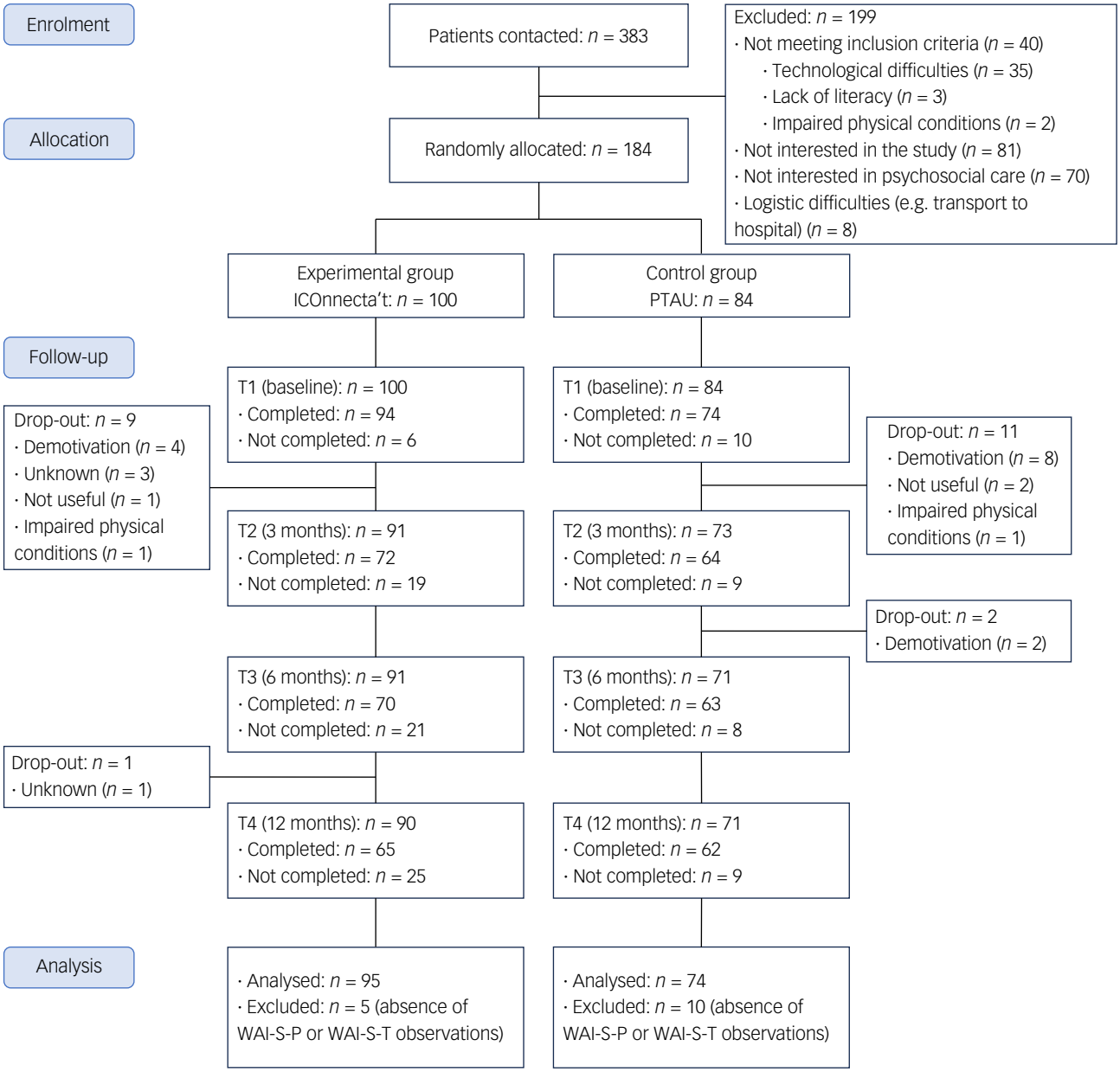

Fig. 2 Participants' flowchart. PTAU, psychosocial treatment as usual; WAI-S-P, working alliance inventory short form, patient version; WAI-S-T, working alliance inventory short form, therapist version.

$P = 0.022$) and communication amount (coefficient [95% CI] = 0.11 [0.02–19], $P = 0.014$) significantly explained the variance in WAI-S-T at T4. In the multivariate model (R^2 adjusted = 0.421), satisfaction (coefficient [95% CI] = −5.98 [−8.91 to −3.05], $P < 0.001$) indicated significant association with WAI-S-T at T4. The other variables were not significant in explaining therapeutic alliance scores (for statistical details, see Supplementary Table 2).

Discussion

The present research extends the knowledge about the development of therapeutic alliance in a digital setting, and particularly in a stepped intervention. To our knowledge, this is the first RCT to compare therapeutic alliance, in both patients and therapists, between a stepped digital intervention and in-person conventional intervention for cancer patients. This research contributes to expanding the literature on the nature of therapeutic alliance in digital contexts while focusing on variables that may be directly associated with the development of a strong therapeutic alliance.

Aim 1: development of therapeutic alliance

From the patients' perspective, current results differ from our first hypothesis and previous research in finding lower therapeutic alliance in the digital intervention compared with the conventional one.[4,23,44,45] Two recent studies with cancer patients indicated that both asynchronous communication via text messages[19] and synchronous communication via video consultations[20] could be perceived by patients as a barrier, making it difficult to establish a fluid dialogue with the therapist, which could explain our results. However, it is important to emphasise that ICOnnecta't patients reported remarkably strong therapeutic alliance, even surpassing

Table 2 Total and subscales therapeutic alliance scores for patients (WAI-S-P) and therapists (WAI-S-T) at T2, T3 and T4, and intention-to-treat repeated measures analyses between ICOnnecta't ($n = 95$) and PTAU ($n = 74$)

	T2	T3	T4	Fixed effect			
	Mean (s.d.)	Mean (s.d.)	Mean (s.d.)		Estimates (s.e.)	95% CI	*P* value
WAI-S-P							
Total				Group	−7.31 (2.14)	[−11.52, −3.10]	0.001*
ICOnnecta't	63.31 (18.75)	66.58 (17.07)	62.96 (20.66)	Time T2–T3	2.99 (1.25)	[0.55, 5.44]	0.017*
PTAU	70.58 (13.20)	73.22 (10.33)	70.97 (16.00)	Time T2–T4	−0.02 (1.25)	[−2.47, 2.43]	0.985
Goals				Group	−2.81 (0.72)	[−4.23, −1.40]	<0.001*
ICOnnecta't	20.57 (6.85)	22.18 (5.99)	21.62 (7.07)	Time T2–T3	1.17 (0.47)	[0.24, 2.10]	0.013*
PTAU	24.05 (4.53)	24.66 (3.84)	24.09 (5.30)	Time T2–T4	0.61 (0.47)	[−0.32, 1.54]	0.197
Tasks				Group	−2.12 (0.73)	[−3.55, −0.70]	0.004*
ICOnnecta't	19.96 (6.59)	21.64 (5.81)	20.80 (6.31)	Time T2–T3	1.57 (0.44)	[0.71, 2.43]	<0.001*
PTAU	22.18 (4.92)	23.59 (3.95)	23.00 (5.87)	Time T2–T4	0.83 (0.44)	[−0.03, 1.69]	0.057
Bond				Group	−1.86 (0.77)	[−3.37, −0.35]	0.016*
ICOnnecta't	22.55 (6.34)	23.07 (5.83)	21.36 (7.32)	Time T2–T3	0.37 (0.44)	[−0.49, 1.23]	0.394
PTAU	24.35 (4.76)	24.53 (4.39)	23.68 (6.07)	Time T2–T4	−0.96 (0.44)	[−1.82, −0.11]	0.028*
WAI-S-T							
Total				Group	−8.05 (1.08)	[−10.17, −5.94]	<0.001*
ICOnnecta't	66.34 (8.86)	67.25 (9.12)	67.49 (9.77)	Time T2–T3	2.07 (0.67)	[0.76, 3.38]	0.002*
PTAU	72.54 (7.26)	76.09 (7.45)	76.61 (9.77)	Time T2–T4	2.43 (0.67)	[1.12, 3.74]	<0.001*
Goals				Group	−2.64 (0.40)	[−3.42, −1.86]	<0.001*
ICOnnecta't	21.06 (3.56)	21.82 (3.58)	22.36 (3.57)	Time T2–T3	1.29 (0.26)	[0.77, 1.81]	<0.001*
PTAU	23.01 (2.80)	24.99 (2.69)	25.16 (2.78)	Time T2–T4	1.67 (0.26)	[1.15, 2.19]	<0.001*
Tasks				Group	−2.50 (0.38)	[−3.25, −1.74]	<0.001*
ICOnnecta't	21.85 (3.34)	22.24 (2.83)	22.15 (3.61)	Time T2–T3	0.60 (0.28)	[0.06, 1.15]	0.030*
PTAU	23.88 (3.13)	24.76 (3.26)	25.09 (3.04)	Time T2–T4	0.70 (0.28)	[0.15, 1.24]	0.012*
Bond				Group	−2.83 (0.37)	[−3.56, −2.10]	<0.001*
ICOnnecta't	23.42 (2.99)	23.26 (3.04)	22.94 (3.70)	Time T2–T3	0.23 (0.23)	[−0.23, 0.69]	0.322
PTAU	25.65 (2.47)	26.38 (2.27)	26.08 (2.87)	Time T2–T4	−0.08 (0.23)	[−0.54, 0.037]	0.722

T2, 3 months since the inclusion; T3, 6 months since the inclusion; T4, 12 months since the inclusion and end-treatment; PTAU, psychosocial treatment as usual; WAI-S-P, working alliance inventory short form, patient version; WAI-S-T, working alliance inventory short form, therapist version.
* $P < 0.05$.

the levels reported in previous studies with an oncological population.[4,27] Additionally, the therapeutic alliance developed within the first 6 months of the intervention and then remained stable until its completion, showing the same pattern in both groups. These findings indicate that breast cancer patients could establish and maintain a strong therapeutic alliance throughout the stepped digital intervention.

A similar pattern emerged from the therapist's perspective, who established high therapeutic alliance through the ICOnnecta't intervention, even though it was significantly lower than that in PTAU over time. Three reasons have been proposed from eHealth reviews to explain this phenomenon. First, therapists might feel insecure about establishing an emotional bond in a digital setting,[23] because they must adapt their behaviour to convey warmth, compassion, and mutual trust to compensate the absence of physical therapeutic contact, and they often lack training in this area.[21] Second, therapists may feel that they are unable to assess the patient accurately and under equivalent circumstances as they would in conventional settings, leading them to perceive their care as superficial.[23] Third, the negative attitudes and expectations that professionals feel towards eHealth could have a negative impact on the perception of the therapeutic alliance established with patients.[44] Nevertheless, our results challenge all these hypotheses: bond scores were higher than the other therapeutic alliance components, and their progression throughout the intervention period was comparable to that of conventional intervention. Moreover, our therapists expressed high satisfaction with the professional eHealth platform, which allowed them systematically to assess and monitor the psychological status of patients. Accordingly, a qualitative study concluded that technologies enabling the understanding of patients' needs and facilitating connection by a different communication method enhance personalisation and prevent the dehumanisation of the intervention therapist' experience, favouring therapeutic alliance and the affective bond.[16]

Table 3 Level of agreement between patients (WAI-S-P total) and therapists (WAI-S-T total) at T2, T3 and T4, for ICOnnecta't ($n = 95$) and PTAU ($n = 74$) groups

	Difference [95% CI]	*P* value	Cohen's *d* [95% CI]	ICC [95% CI]	*P* value
T2					
ICOnnecta't	−3.03 [−7, 1]	0.137	0.2 [−0.07, 0.47]	0.09 [−0.112, 0.285]	0.192
PTAU	−1.96 [−5.2, 1.2]	0.227	0.18 [−0.12, 0.48]	0.152 [−0.077, 0.366]	0.096
T3					
ICOnnecta't	−0.67 [−4.2, 2.9]	0.705	0.05 [−0.2, 0.3]	0.205 [0.00, 0.389]	0.022*
PTAU	−2.88 [−6, 0.3]	0.074	0.32 [−0.04, 0.68]	−0.165 [−0.377, 0.064]	0.922
T4					
ICOnnecta't	−4.54 [−8.8, −0.3]	0.037*	0.27 [0.01, 0.53]	0.148 [−0.054, 0.338]	0.074
PTAU	−5.64 [−9.3, −2]	0.003*	0.43 [0.14, 0.71]	0.178 [−0.05, 0.389]	0.063

ICC, intraclass correlation coefficient; PTAU, psychosocial treatment as usual; WAI-S-P, working alliance inventory short form, patient version; WAI-S-T, working alliance inventory short form, therapist version; T2, 3 months since the inclusion; T3, 6 months since the inclusion; T4, 12 months since the inclusion and end-treatment.
* $P < 0.05$.

Overall, we can explain the high therapeutic alliance established by therapists in the stepped digital intervention, although future deeper explorations are needed to understand the differences compared with conventional interventions.

Aim 2: agreement between patients and therapists

The second hypothesis was partially supported in this objective. The literature comparing therapeutic alliance between patients and therapists generally reports lower therapeutic alliance in therapists.[16–18,21] However, our results showed that while there were no differences during the interventions, by the end, therapists reported higher therapeutic alliance than patients. Furthermore, as previous authors have found,[18] there was no agreement between them in the perception of this relationship at any time during the interventions, even if a weak agreement was observed at 6 months in ICOnnecta't. The fact that therapists may have higher expectations regarding interventions and therapeutic alliance could be an explanation for why this occurs in both groups.[46] It is important to address this phenomenon in future studies because the disagreement in the perception of therapeutic alliance could impact the therapeutic process and adversely affect intervention outcomes.[47]

Aim 3: variables associated with therapeutic alliance in ICOnnecta't intervention

The primary challenge of the present study was to identify unique factors of the stepped digital intervention that could influence the development of therapeutic alliance. In the ICOnnecta't intervention, as a stepped model, the interaction between patient and therapist only occurs when a patient actively reports her psychological status, and psychosocial needs are detected. Furthermore, therapists adapt their communication approach and sometimes combine different formats of care delivery depending on patients' needs and symptoms' severity. In line with the third hypothesis, our results indicated that the usability and satisfaction with the ICOnnecta't app were associated with the therapeutic alliance in patients, while satisfaction with the monitoring professional platform was associated with therapeutic alliance in therapists. In line with recent studies, digital tools seem to be key factors in the patient-therapist relationship,[24,25] because technological mediation may influence both the quality and perception of verbal and non-verbal communication directly impacting the therapeutic alliance.[17] Doukani et al[24] went one step further proposing a new conceptual framework of the Bordin's therapeutic alliance model in the context of a low-intensity digital intervention for depression. This model adds a fourth therapeutic alliance component named *usability heuristics*, which involves the digital tool elements that promote active engagement: ease of use, accessibility, interactivity, aesthetic appeal and self-directed. According to Cataldo et al,[17] incorporating tools and platforms as an element in therapeutic alliance development could improve the quality of clinical studies by facilitating its design and analysis. To do this, various adaptations of the WAI have been proposed, although all of them were designed for self-guided interventions.[25] This approach assumes that the patient establishes a relationship with the technology as there is no therapist involved providing the intervention, so they could not be used in our ICOnnecta't intervention described herein.

Regarding the other potentially associated variables, it is worth noting that neither the type (text messages, video consultation) nor the amount of communication was related to therapeutic alliance in both patients and therapists, contrary to the third hypothesis. This implies that they could develop a strong therapeutic alliance regardless of the quantity of interactions or the intervention format employed, even if there was minimal or no communication. In accordance with our findings, Richards et al[16] suggested that text messages offer patients a genuine sense of care, interest and therapeutic process control as they could contact their therapist when they decided, and with the frequency they feel comfortable with. Moreover, video consultations give patients control over personal space and a sense of shared responsibility over the communication tool employed.[22] These features likely enhance the feeling of connection, presence and empowerment, even if they almost never actually interact.[16,22] Besides, interaction through these communication formats did not appear to have a differential impact on therapeutic alliance in our study. Given its similarity to conventional settings, video consultations should establish stronger therapeutic alliance compared with other digital interventions.[17] However, text messages could promote the *online disinhibition effect*, which would explain our results. This occurs when messages encourage emotional expression by converting thoughts and feelings into words to compensate for the absence of non-verbal cues which would facilitate the establishment of a stronger bond.[20,45] Therefore, the lack of association found in our study between therapeutic alliance and the type and amount of communication, combined with the literature discussed here, may suggest that the sense of control, flexibility and availability provided by digital communication methods could support the development of a strong therapeutic alliance, regardless of the format or frequency of interactions. Concerning this, the lower therapeutic alliance observed in ICOnnecta't compared with PTAU could be partially attributed to the limitations of the WAI in capturing and assessing all the added values that digital communication methods can bring to the therapeutic relationship (i.e. increased flexibility, a greater sense of control for patients, and enhanced accessibility to therapists), underestimating the therapeutic alliance developed.[22]

Limitations

The present study has limitations that should be considered to interpret the results with caution. First, the sample size for this RCT was estimated considering the hospital anxiety and depression scale (HADS), not the WAI-S, as it was the main outcome to assess the effectiveness of ICOnnecta't.[28] Moreover, there appears to be an uneven sample allocation between intervention groups. Randomisation was conducted by an independent researcher using a list of randomly generated numbers, and the enrolment period had to conclude with this random disparity. Although no significant difference in acceptance, attrition and retention was found between groups, the control group had excluded more final data from the analysis, which increases the sense of sample disparity. Second, the study focused on recently diagnosed breast cancer women. This limits the generalisability of the results to other genders, cancer diagnoses and cancer stages, who may have different therapeutic alliance needs and eHealth approach requirements. Third, as two therapists did not participate in PTAU, the LMM could not be adjusted by the therapist to control for potential differences. Fourth, the type and amount of communication did not seem to have a differential impact on therapeutic alliance in our study. Future research with larger sample sizes could better explore whether these variables are truly associated with therapeutic alliance or not. Finally, it is likely that there are additional variables influencing therapeutic alliance that were not considered in this study, such as the rate of app use,[26] treatment adherence,[5] attrition with the intervention,[4,18] or other usability heuristic variables (e.g. accessibility, interactivity, aesthetic appeal).[24] Future research could delve deeper into these aspects to provide a more comprehensive understanding of factors that impact therapeutic alliance in digital interventions and how they may be considered in the design of those interventions.

Conclusions

This study enhances our understanding of the development of the digital therapeutic alliance, particularly within a stepped intervention. Our findings expose the potential of these interventions to establish and maintain a strong therapeutic alliance, both in patients and therapists. However, there was no agreement in the perception of therapeutic alliance between them that could potentially affect the therapeutic process. Notably, neither the type nor amount of communication impacted the development of patients' therapeutic alliance, suggesting that sense of control, flexibility and availability of digital communication could foster the sense of care, interest and affective connection. Furthermore, therapists expressed high satisfaction with the digital platform, suggesting that stepped tools could effectively support the management of the therapeutic process. Finally, this study reveals the contribution of usability and satisfaction with the digital tools in the level of therapeutic alliance. It seems crucial to incorporate and evaluate digital tools and platforms as integral components of the therapeutic alliance, while considering *usability heuristics* and digital empowerment as therapeutic process factors in digital interventions. A more comprehensive understanding of these factors will enhance the interventions' design to facilitate the therapeutic process and improve their effectiveness on mental health outcomes.

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Supplementary material

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Data availability

The data are available on request from the corresponding author. The data are not publicly available due to privacy of research participants.

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Author contributions

A.F.-V.: funding acquisition; conceptualisation; project management; methodology; carried out the experiment; data curation; writing original draft. J.C.M.: conceptualisation; methodology; formal analysis; oversight original draft. A.S.-S.: carried out the experiment; data curation; oversight original draft. A.A.-O.: carried out the experiment; oversight original draft. E.J.-L.: carried out the experiment. M.S.-B.: oversight original draft. L.C.-S.: oversight original draft. G.F.: supervision. C.O.-A.: leadership; funding acquisition; supervision. All authors: writing review and editing; approve the final version of the manuscript.

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Declaration of interest

None.

Transparency declaration

The manuscript is an honest, accurate, and transparent account of the study being reported; no important aspects of the study have been omitted; and any discrepancies from the study as planned have been explained.

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