

Mental health-related impact applying a scalp cooling technology solution in chemotherapy: a scoping review

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Abstract

Background and Objective

A scalp cooling system, particularly, a digitised scalp-cooling system, is currently assuming an important role during adjuvant treatment within the oncological setting, promising the prevention of hair loss and turning an efficient procedure to reinforce the mental health of patients during chemotherapy by preventing chemotherapy-induced alopecia (CIA). We conducted a scoping review to map the literature on the efficacy of the scalp cooling technology in chemotherapy. We focused on the efficacy of the scalp cooling system in preventing CIA and the associated mental health effects, such as reducing mood changes, depression, anxiety, anger, sleep disorders, and fatigue.

Methods

We performed a systematic search of MEDLINE via PubMed, Embase, Web of Science, PsycINFO, and Scopus in May 2020. We conducted a descriptive analysis of the characteristics of the included literature. Based on the exclusion/inclusion criteria, a total of 17 articles were included in the scoping review process.

Results

This review demonstrated the lack of research on the efficacy of adopting the scalp cooling system as preventive care for the well-being of patients through the prevention of their hair loss. Nevertheless, research on this topic is progressively increasing, and future studies should address specific key points.

Conclusion

This study aimed to identify emerging and urgent research domains in order to design better clinical outcomes for innovative solutions, integrating the physical and mental health of oncological patients in survivorship.

Introduction

Cancer patients face a number of disease-related challenges that lead to clinically relevant mood disorders, psychological distress, and depression (Linden et al., 2012; Seiler & Jenewein, 2019; Di Giacomo et al., 2019). In primary treatment, patients have to deal with chemotherapy and its associated burdensome physical effects, as well as effects on body image (Mehnert et al., 2018). One such side-effect is chemotherapy-induced alopecia, a temporary form of hair loss that could influence the mental health of patients who suffer from it. In order to support patients dealing with the side effects of adjuvant treatments, the scalp hypothermia technique was introduced as a preventative measure against the development of CIA. Technological innovations in clinical medicine, specifically in oncological treatments, allowed for the introduction of a scalp cooling system aimed at preventing hair loss during chemotherapy treatment. Currently, DigniCap, a digitized scalp-cooling system, is assuming an important role in the clinical setting during adjuvant treatment, promising hair loss prevention and allowing an efficient procedure to reinforce the mental health of patients during chemotherapy by avoiding CIA. DigniCap comprise a refrigerator unit and a control unit integrated into a mobile cabinet and connected to a tight-fitting cooling cap. This system maintains a constant scalp temperature of + 5°C during all chemotherapy treatments (lasting during the entire session, for minimum of 4 hours or longer, as part of the planned chemotherapy regimen). The application of this digital solution in medical treatments is primarily based on experimentation data demonstrating reduction in the rate of hair loss as the primary outcome for a higher quality of life during chemotherapy and post-primary treatment (Giarratano et al., 2019). The increasing application of scalp cooling systems in chemotherapy has led to the emergence of an innovative solution in clinical medicine related to mental health during oncological treatments.

The aim of this study is to map the literature regarding the mental health influence of the DigniCap system's application in chemotherapy treatments, defining the strengths and weaknesses of the research topic. This scoping review focuses on the efficacy of the DigniCap system in preventing CIA as well as its influence on mental health, particularly, in reducing mood changes, depression, anxiety, anger, sleep disorders, and fatigue. Specifically, we wanted to quantify and synthesize the studies

conducted thus far regarding the efficacy of the mental health effect of the digitised scalp cooling systems and highlight the emerging key points for future research protocols. Ideally, our findings could aid in the harmonisation of the implementation of cancer care toward high quality of life in survivorship. The scope of this review is to maximise the value of previously published findings and to harmonise future study approaches, drawing on potential future challenges and prompting key components for future research.

Methods

We conducted a scoping review to map the literature on the efficacy of the DigniCap technology in chemotherapy. The framework outlined by Arksey and O'Malley (2005) in their methodological paper on scoping studies was adopted. Our aim was 1) to summarise and disseminate current available evidence for the impact of DigniCap on the psychological needs of oncological patients, and 2) to propose key points for future research.

Specifically, the research objectives of this review have been:

1. to summarise the current evidence on the DigniCap's impact on the quality of life and wellness of patients;
2. to identify gaps in the literature that may require further research; and
3. to identify relevant research questions, particularly, the determinants of future implementation approaches.

Search strategy

We performed a systematic search of MEDLINE via PubMed, Embase, Web of Science, PsycINFO, and Scopus in May 2020 with the terms 'dignicap', 'scalp cooling', 'scalp hypothermia', and 'hypothermic cap', combined with 'quality of life', 'wellness', and 'clinical psychology', published from May 2000 to May 2020.

Inclusion and exclusion criteria

We included all literature related to the Dignicap system published in English until 30 May 2020 without restrictions. This comprised reviews, clinical studies, basic research, epidemiological studies, and clinical trials. However, we excluded news reports that were not published in scientific journals and articles whose full text we were unable to access despite contacting the authors.

Article selection and data extraction

Two reviewers independently screened all titles, abstracts, and full texts and resolved disagreements by consensus or consultation with a third reviewer. The following information were extracted: (i) title, (ii) authors, (iii) journal, (iv) publication or posted date, (v) type of article/study, (vi) topic, (viii) objectives of study, and (ix) results.

Statistical analysis

We conducted a descriptive analysis of the characteristics of the included literature. We described the source, publication date, type of article/study, and topic of article/study to examine the existing gaps in research. We categorised the literature into reviews, clinical studies (including randomised controlled trials and observational studies), basic research, epidemiological studies, editorial comments, and other categories if identified. We conducted this scoping review in accordance with the PRISMA-ScR Checklist (Tricco et al., 2018).

Results

Search results

Our initial search returned n 35 papers from our database. After duplicate and inadequate articles were removed, we identified n 20 records that underwent title and abstract review for relevance. Then, three articles were excluded during full-text review..

Figure 1 illustrates the study selection flowchart.

Characteristics of included articles/studies

The articles included in the scoping review were cohort studies, review studies, clinical trials, and basic research.

Source of articles/studies

All articles/studies have been published in peer-reviewed journals. The journal with the highest number of published articles was Cancer Research (n = 4,23.5%).

Table 1
a - Publishers of articles/studies

Characteristics of articles/studies		Number	%
Platform Publication: <i>Journal</i> (= 17)	Cancer Research	4	23,5
	Breast Cancer Research and Treatment	2	11,8
	JAMA	1	5,9
	The Breast Journal	1	5,9
	Breast Journal	1	5,9
	Supportive Care in Cancer	1	5,9
	Springerplus	1	5,9
	Asia-Pacific Journal of Oncology Nursing	1	5,9
	Expert Review of Dermatology	1	5,9
	British Journal of Cancer	1	5,9
	Reviews on Recent Clinical Trials	1	5,9
	Future Oncology	1	5,9
	Current Oncology	1	5,9
First Author' Country	Italy	5	29,4
	USA	4	23,5
	Germany	2	11,8
	Australia	2	11,8
	The Netherlands	2	11,8
	Mexico	1	5,9
	Switzerland	1	5,9
Publication or posted date	November-2019	1	5,9
	October-2019	1	5,9
	July-2019	1	5,9
	February-2019	1	5,9
	January-2019	1	5,9
	September-2018	1	5,9
	July-2018	1	5,9
	February-2018	1	5,9
	February-2017	2	11,8
	December-2016	1	5,9
	April-2016	1	5,9
	February-2016	1	5,9
	March-2015	1	5,9

Characteristics of articles/studies	Number	%
September-2014	1	5,9
December-2012	1	5,9
February-2011	1	5,9

Type of articles/studies

The types of published articles are reported in Table 1b.

The platform of publication is generally on oncological outlook (Current Oncology, Cancer Research, and Breast Cancer Research & Treatment), involving mostly Italian and American authors. Moreover, looking at the posted date of publication, interest in this topic is seen to be increasing progressively over time.

Table 1
b - Characteristics of DigniCap articles/studies in breast cancer chemotherapy.

Characteristics of articles/studies	Number	%
Topic	Efficacy on CIA Prevention	14
	Quality of Life	9
	Emotional features (anxiety, depression, body image, distress, satisfaction)	7
	Tolerability and safety	4
	Attitude & knowledge on SC	3
Type of articles/studies	Cohort study	6
	Basic research	3
	Clinical trial	2
	Review	2
Type of study poster	Cohort study	2
	Clinical trial	1
	Basic Research	1

Table 1b reports the typologies of the studies conducted to date. The cohort study design seemed to be more widely applied than the other study designs. By contrast, there was a lower rate of published basic research and clinical trial study designs. Finally, the research topic that had been more relevant in the literature was the investigation of CIA prevention efficacy. Following this was the focus on the impact on psychological needs (quality of life and emotional traits).

In Table 2, screened articles highlighting the details of each research protocol were grouped into three study designs: clinical trials (n = 3), cohort studies (n = 8), and basic research (n = 4). Clinical trials (Cigler et al., 2017; Smetanay et al., 2018; Munzone et al., 2019) have been conducted mostly from a multicentric perspective and observational studies.

Table 2 - Details of experimental studies analyzed in this scoping review

TYPE OF STUDY	AUTHORS	KEYWORD AIM	TOPIC	STUDY DESIGN	STATISTICAL ANALYSIS	SAMPLE SIZE	TARGET SAMPLE	TESTS	OUTCOMES
CLINICAL TRIAL	Cigler et al. (2017)	HAIR LOSS + QoL	CIA + QoL	Prospective non randomized open label; treatment control multicenter study	Risk ratios using Mantel-Haenszel random effects model use to assess differences	N.117 patients (N.101 received scalp cooling using Dignicap and N.16 were controls (no scalp cooling))	Women, age >18 years, stage I or II breast cancer receiving neo/adjuvant chemotherapy regimens. Women who chose not to undergo scalp cooling were enrolled as controls.	BR23; BIS; hair loss self-assessment with treatment success defined as <=50 hair loss	66.3 % of patients using Dignicap achieved treatment success. Women with BC receiving DIGNICAP vs control during chemotherapy: were significantly less likely to lose >50% of their hair; felt significantly more physically attractive; were significantly less dissatisfied with their appearance when dressed; regarded the importance of hair significantly more
	Smetan et al. (2018)	EFFICACY + TOLERABILITY + QoL	CIA + QoL	Monocentric prospective randomized open trial	Descriptive statistics; Chi-squared test; per-protocol analysis; Intention-to-treat (mITT) sample	N. 79 (n. 41 scalp cooling (CAP) group; n. 38 no scalp cooling NoCAP group)	Females >18 years old; breast cancer stage I-III; ECOG 0-1; planned chemotherapy	Dean Scale; medical staff rate of wig/scarf use, tolerability, hair pull test, trichogram; EORTC QLQ-C30; BR23	1) Hair preservation was achieved in 39.3% of patients in the CAP compared to 0% in the NoCAP arm in the per protocol analysis (p < 0.001. 2) Main reasons for drop-out were hair loss, adverse events (CAP), and randomization into control arm. No differences in efficacy between anthracycline-based and non-anthracycline-based regimens; 3) QoL did not differ between the study arms
	Munzon et al. (2019)	HAIR LOSS + QoL	CIA + QoL	Prospective two-stage design clinical trial	Descriptive statistics; Cohen's Kappa,	N. 139 Breast Cancer patients	Median age 47 years (range: 28-65); of female	Primary endpoint: Dean's scale. Secondary	56 out of 131 evaluated patients successfully

					Dean's score; Repeated measured ANOVA; linear transformation to standarize raw scores		patients with diagnosis of early-stage breast cancer and with a planned course of chemotherapy in the adjuvant setting.	endpoints: Technology Acceptance Model (TAM) Questionnaire, EORTC-QLQ-C30, EORTC-QLQ-BR23, .	prevented HL (43%, 95% CI: 34-51%). 24 (32%) patients discontinued the scalp cooling because of alopecia or scalp-cooling related AE, 3 patients had missing information on CIA, and 48 patients (64%) had a HL greater than 50% after CT
COHORT STUDY	Rugo et al.. (2012)	HAIR LOSS + QoL	CIA + QoL	Prospective study	Not specified	N. 20 patients under CTX regiment	Women with stage I breast cancer	Dean Scale; QoL test; time to quality of hair re-growth and impact of Hair Loss on treatment decisions questionnaire	19 of 20 patients (95%) completed all CTX using the DigniCap System. By independent panel (IP) assessment, 15 patients (75%) had a maximum of \leq grade 2 hair loss
	Fehr et al. (2016)	HAIR LOSS + SATISFACTION	CIA + SATISFACTION	Prospective study	Descriptive statistics; multivariate analyses	N. 55 female patients	Cancer patients=> 18 years old; planned neoadjuvant or adjuvant chemotherapy; breast, endometrial, or ovarian cancer; patients (N 42, 76% breast cancer; N12, 22% ovarian cancer; N 1, 1.8% endometrial cancer). Mean age 56 ds 12 years (range 32-79 year	Photographs of the patient's head; self-administered satisfaction questionnaire; case report form using WHO grading of acute and subacute toxicity for alopecia	78% underwent scalp cooling until completion of chemotherapy. Younger women and those receiving paclitaxel weekly or paclitaxel-carboplatin experienced less alopecia
	Rugo et al., (2017)	HAIR LOSS + QoL	CIA + QoL	Multicenter prospective	Descriptive statistics; Fisher exact test; exact method based on binomial distribution; 2-sided x2 test; per-protocol analysis	N. 122 (n.106 in the scalp cooling group; n. 16 in the control group)	Females \geq 18 years old; stage I or II breast cancer; planned neoadjuvant cytotoxic therapy	Dean scale; Patient Symptom Survery; EORTC-QLQ	Less hair loss at 4 weeks after treatment. 3 of 5 quality-of-life measures were significantly better 1 month after the end of chemotherapy in the scalp cooling group.
	Chan et al. (2018)	HAIR LOSS + MOOD + BODY IMAGE	CIA + PSY	Prospective study	Descriptive statistics; Bonferroni correction; paired-	N. 60 (categorised according to chemotherapy regimen: n.20	Females >18 years old; stage I-III breast cancer; recommended	Dean scale; PHQ-9; GAD-7; BIS; information on the use of any	33% of patients reported Minimal Hair Loss. Patients

				samples t-test; logistic regression; weighted kappa score	in Cohort 1 TC/TCH; n.20 in Cohort 2 TAC; n.20 in Cohort 3 FEC-D/AC-P)	to receive adjuvant or neoadjuvant chemotherapy regimens (TC, TCH, TAC, AC, AC-P, FEC-D); conversant in English; provided signed consent; agreed to undergo follow-up for 10 years	head covering, usefulness and probability of cap future use and adverse events	receiving taxane-only chemotherapy had the highest rate of MHL (45%). Patient-reported anxiety reduced significantly in all patients, but no difference was observed for depression or body image irrespective of degree of hair loss. Scalp cooling relater adverse events were uniformly of low grade and all resolved.
Vassalli et al. (2018)	EFFICACY + SAFETY + QoL	CIA + QoL	Prospective study	Descriptive and inferential statistics	N. 49 patients (mean age 51 years)	Women with early breast cancer who receiving neo/adjuvant treatment.	Dean's alopecia scale; Digital photographs; Visual Analogical Scale (VAS); EORTC QLQ-C30.	1) Fifteen patients (30%) stopped the treatment because of loss of hair in 9 patients. At the end of chemotherapy, 13 patients (27%) had no loss of hair (Dean score 0), 25 patients (51%) had a minimal loss of hair (Dean score 1 2) There wasn't a significant difference between mean score value of QLQ-C30 at baseline and after chemotherapy and between the groups with and without hair loss
Giarratano et al. (2019)	EFFICACY + TOLERABILITY + PATIENT JUDGMENT ON PERFORMANCE	CIA + PATIENT JUD PERFORMANCE	Prospective study	Descriptive statistics; χ^2 test; Mann-Whitney test	N. 135 (categorised according to chemotherapy regimen: n.35 TC; n.31 Txl; n. 43 EC-Txl; n.26 Txl-EC)	Females, range age 27-76, breast cancer stage I-III, ongoing adjuvant/neo-adjuvant CT	Dean Scale; Patients' self-assessment questionnaires on scalp cooling tolerability and performance	The rate of success in preventing alopecia was 77% (104/135) at 3 weeks from the start of CT and 60% (81/135) at 3 weeks from the end of treatment
Prochilo T. et al., (2019)	HAIR LOSS + TOLERABILITY + DISTRESS	CIA + PSY + SAFETY	Prospective study	Cohen test; Wilcoxon	N. 27 patients	Female =>18 years; stage I-III Breast	Dean's scale; VAS; Photographs;	24 pts (89%) completed the treatment; 3

		ANXIETY DEPRESSION + SAFETY			rank sum test.		Cancer; planned adj CT	Common Terminology Criteria for Adverse Events version 4.0 (CTCAE v 4.0). Comfort analogic scale (AS) for tolerability. An AS for pain evaluation. Hospital Anxiety and Depression Scale (HADS)	pts (11%) prematurely interrupted use of the scalp-cooling device due to inefficacy. After the last cycle of chemotherapy, the number of patient who perceived a HL < grade 2 was 16 (59%). The hair retention reported by operators has been higher (78%). 81.5% of patients well tolerated the treatment.
	Orlando et al., (2019)	HAIR LOSS + QoL	CIA + QoL	Prospective study	Descriptive statistics	n.127 Breast Cancer patients	Early-stage BC candidacy to neo/adjuvant anthracycline and/or taxane chemotherapy; age range 31- 75 yo	Dean's alopecia scale, EORTC QLQ- C30 and BR-23	The success rate in preventing CIA was 71.7%. The use of head cover (wig, cap or scarf) was very low (29.9%). The tolerability was excellent, with low rate of withdrawal (17.3%), mainly due to unsatisfactory hair preservation (9.4%).
Basic Research	Campos- Gomez, et al. (2016)	EFFICACY + SAFETY + QoL	CIA + QoL	Observational study	Descriptive and inferential statistics	N. 210 women with breast cancer (n. 110 in scalp- cooling system group; n. 100 in no scalp-cooling group)	Women with breast cancer receiving neo or adjuvant	World Health Organization (WHO) criteria; Photo documentation; EORTC QLQ- C30; EORTC- QLQ-BR23	1) Nurses' ratings indicated that hair loss frequency was constantly lower, at each cycle of chemotherapy. 2) Differences between the two groups were statistically significant at cycles 1 and 4 (P < 0.047). 3) higher well- being was found in successfully scalp-cooled patients, as indicated by a general better health-related quality of life, whereas unsuccessfully scalp-cooled

								patients reported lowest well-being
Shaw et al. (2016)	MOTIVATION TO USE + UNMET NEEDS	PATIENT	Qualitative study	Thematic analysis of focus groups and interviews using a constant comparative methodology; theoretical saturation of themes; open, axial and selective coding	N. 17 (n.11 in the scalp cooled group (n.9 focus groups, n.2 interviews); n. 6 in the non-scalp cooled group (n.5 focus group, n.1 interview)	Females; age range 43-74; breast cancer (BC) diagnosis between October 2010 and March 2014; had and completed chemotherapy treatment; treated for BC after 2010; conversant English	Semi-structured interviews and focus groups on open-ended questions and specific probes recorded and transcribed verbatim	1) Participants highlighted unmet information need associated with the process of scalp cooling, hair care and tolerability issues. Faster regrowth was a motivator to continue treatment 2) Non-scalp-cooled patients also viewed scalp cooling positively, although were ambivalent about whether they would use the technology in the future.
Friedrichs et al. (2014)	HAIR LOSS + SATISFACTION + ADVERSE EFFECTS	CIA + SATISFACTION + SAFETY	Observational study	Descriptive statistics	N. 83 patients	Females >=18 years old with breast cancer diagnosis	VAS; patient's information on head cover; hair loss and regrowth rating by an expert based on a set of photographs; a modified version of Dean's scale	64/83 (77%) patients finished CT and SC treatment. 19 patients dropped-out due to unspecified intolerance (10.8%), hair loss (6.0%), cancer related emergency cases or disease progression (3.6%) and SC-related side effects (2.4%) (feeling cold, headache).
Peerbooms, et al., (2015)	ATTITUDE AND KNOWLEDGE ON SC	ATTITUDE AND KNOWLEDGE ON SC	Observational study	Descriptive statistics	N.177 patients, N.49 nurses, N.100 MDs	Ex breast cancer scalp-cooled and non-scalp-cooled patients, nurses and Medical Doctors from SchoolingCap and non-SC hospitals	self-developed questionnaires	The majority of MDs and nurses were satisfied with the results of SC, as were SC patients. Seventy percent of SC patients with insufficient results (20/52) reported to mind it very much. With expected success rates of 35% and 50%,

									respectively, 36% and 54% of patients would use SC again.
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In cohort study designs (Rugo et al., 2012; Fehr et al., 2016; Rugo et al., 2017; Vassalli et al., 2018; Chan et al., 2019; Giarratano et al., 2019; Prochilo et al., 2019; Orlando et al., 2019) prospective observational studies have been conducted mostly in multicentric research, focusing on CIA and quality of life, satisfaction, and patient-reported performance variables in an oncological population diagnosed with breast cancer. All studies reported a good rate of success for the DigniCap technology associated with chemotherapy treatment, particularly, regarding hair loss (average: 25% of CIA). The included studies reported an average of 30% drop-out rate from the scalp cooling application. Finally, an average of 10% of patients reported adverse events (headache) and/or were discontinued from the treatment due to feeling cold. Regarding the positive psychological impact of the DigniCap technology, preventing CIA and improving the quality of life was not significantly detected. Vassalli et al. (2018) reported no significant changes in the quality of life pre- and post-treatment, and even reported an increase in fatigue; by contrast, only anxiety seemed to have decreased in this cohort. Similarly, Pochilo et al. (2019) reported a decrease in anxiety level with an increase in depressive thoughts.

The basic research category (Friedrichs et al., 2014; Campos-Gomez et al., 2015; Peerbooms et al., 2015; Shaw et al., 2016) are composed of three observational studies and one qualitative study. Observational studies detected higher well-being in successfully scalp-cooled patients, as indicated by a generally better health-related quality of life associated with the conservative effect of the DigniCap technology for hair loss. A qualitative study offered a thematic analysis of the patient experience of scalp cooling: the promise of faster regrowth seemed a motivator for adherence to the DigniCap application.

In Table 3, review studies (n = 2) are reported. Breed’s review (2011) focused on the physical impact of DigniCap technology in chemotherapy, analysing hair loss measurements. Further, the review offered a general overview of CIA and scalp cooling. Subsequently, Marks et al. (2019) conducted a systematic review to evaluate the use of scalp cooling for CIA and quantitative quality of life measures. The comprehensive analysis evidenced by a few studies (4 of the 13 studies published before October 2018) concluded that scalp cooling was associated with significant improvements in quality of life measures; 8 (62%) determined that there were either non-significant or no improvements, and 1 (7.7%) provided a mixed conclusion. Although 2 (50%) randomised controlled trials demonstrated that scalp cooling can effectively prevent CIA depending on the chemotherapy regimen, these studies did not show that successful hair preservation was associated with improved quality of life measures.

Table 3 - Details of review paper

TYPE OF STUDY	PAPER	KEYWORD AIM	TOPIC	STUDY DESIGN	SAMPLE SIZE	TARGET SAMPLE	TESTS	OUTCOMES
REVIEW STUDIES (N. 2)	Marks et al. (2019).	QoL + ANXIETY DEPRESSION + BODY IMAGE	QoL + PSY	Systematic review	13 studies (4 randomized clinical trials, 8 cohort studies, and 1 cross-sectional study)	Primary clinical studies that reported on a quantitative QoL measure. All studies investigated use of scalp cooling to prevent CIA in breast cancer patients, and the majority included a control group of non scalp-cooled patients.	EORTC QLQ-C30, QLQ-BR23, GAD, Study-specific questionnaire on distress, HADS, BIS, MBA, PHQ-9, VAS, WHO-5.	4 (31%) of the 13 studies concluded that scalp cooling was associated with significant improvements in QoL measures; 8 (62%) determined that there was either non-significant or no improvements; and 1 (7.7%) provided a mixed conclusion. Although 2 (50%) RCT demonstrated that scalp cooling can effectively prevent CIA depending on the chemotherapy regimen, these studies did not show that successful hair preservation was associated with improved QoL measures.
	Breed et al. (2011).	HAIR LOSS	CIA	Expert Review	N.58 scalp cooling publications and n.3 personal communications (n.7 randomized studies, with and without scalp cooling; n.6 nonrandomized studies with statistical analysis; 11 nonrandomized studies with control groups, without statistical analysis; n.36 studies without controls)	Not specified	patient's information on head cover; hair loss and regrowth rating by an expert based on a set of photographs; a modified version of Dean's scale	Scalp cooling is by far the best method to reduce CIA. Concerns about the protection of malignant cells in the scalp skin by scalp cooling have been proven to be exaggerated. The majority of patients tolerate scalp cooling very well. Scalp cooling is cost-effective when compared with purchasing wigs and other head covers. Scalp cooling is effective but not for all chemotherapy patients.

The screened reviews showed increasing interest in the DigniCap technology over time, and implemented investigations to analyse the magnitude of impact on mental health of oncological patients during and after chemotherapy intervention.

Discussion And Conclusion

The aim of this scoping review was to map and determine the current literature regarding the mental health impact of DigniCap technology applied to chemotherapy treatment in terms of quality of life and wellness of oncological patients. Considering the exclusion/inclusion criteria, a total of 17 articles were included in the scoping review process.

The DigniCap technological solution was designed to reduce the distressing factor induced by CIA as a side-effect of exposure to chemotherapy in oncological patients. This innovative solution aimed to be a preventive intervention that could improve patient care.

This review has demonstrated the lack of research conducted on the efficacy of the DigniCap system adoption as preventive care for the well-being of patients through the prevention of their hair loss. Progressively, researchers have investigated the efficacy of the DigniCap technology for measuring physical preservation, taking into account the rate of hair loss and measuring the degree of satisfaction. Innovative solutions should be better studied by considering mental health-related effects during pharmacological treatment and post-treatment. Our results showed a lack of investigation focused on well-being and emotional impact indexes, as well as the patient-oriented perspective for quality of life. The implementation of research in this area, particularly, the progress in the number of research protocols on this topic, are increasing. Future research should address these key points:

1. DigniCap-targeted aims for mental efficacy
2. Consent about what constitutes a successful rate during DigniCap use
3. Mental health outcomes of DigniCap use

DigniCap-targeted aims for mental efficacy. The main objective of this study was to evaluate hair quantity (preserved or lost) as a measure of quality of life in terms of mental health and well-being. According to Marks et al. (2019), the correlation between successful hair preservation and improved quality of life has not yet been verified, even if studies focused on this topic apply different evaluation systems. Targeted aims should be addressed and tailored to develop DigniCap-specific measurements for the quality of life of cancer patients. Moreover, the associated effect of DigniCap application should be expanded to the evaluation of the patient's mental health, and not just hair measurements. Over time follow-ups could be able to explain mental health efficacy and/or adverse effects.

Consent about what constitutes a successful rate during DigniCap use. The scoping review highlighted the lack of consent regarding what constitutes the scalp cooling success rate. Researchers have applied evaluation processes based on various tests and measures: hair preservation rate, fast regrowth rate, growth rate time, heterogeneous patient reports, and medical reports. However, future research should focus on mental health effects, paying attention to the personality, psychological traits, and social determinants of patients as influencing factors for the successful impact of the technological solution (DigniCap) in chemotherapy. Qualitative and quantitative assessments would address compound wellness and quality of life endpoints.

Mental health outcomes of DigniCap use. The efficacy of the DigniCap system should be better tested. Preventive interventions for better adherence and successful effects of DigniCap treatment could be performed. Structured and accurate informative psychological mediation could be developed to mitigate the negative effects (mood issues) and boost the potential positive mental impact on quality of life and well-being during treatment, and even more after the treatment.

Clinical Implication. Guidelines and recommendations might be identified in order to reduce unexpected psychological distress, personal unmodulated expectations, drop-outs, and a lower sense of well-being. Lastly, aesthetic learning and self-caring should be tested as an adjuvant individual action to improve the psychological adaptation process of patients to the intensive clinical treatment, preventing mental distress during medical pathways.

Limitations. The limitation of this review is the low number of studies that met our inclusion criteria. This limit highlights the need to improve research interest in this topic, as well as on the direct and quick impact to the clinical practice of oncological treatments. A better tailored clinical pathway can enhance the exploitation of the potential of innovative technological solutions in chemotherapy.

Declarations

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This study did not receive funding from any source.

Conflict of Interest

The authors declare no conflicts of interest.

Availability of data and material: Data will be available behind request to the Authors

Code availability: N/A

Authors' contributions: RJ elaborated data, GF statistical analysis, DDG conceptualization

Ethics approval: N/A

Consent to participate: N/A

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Figures

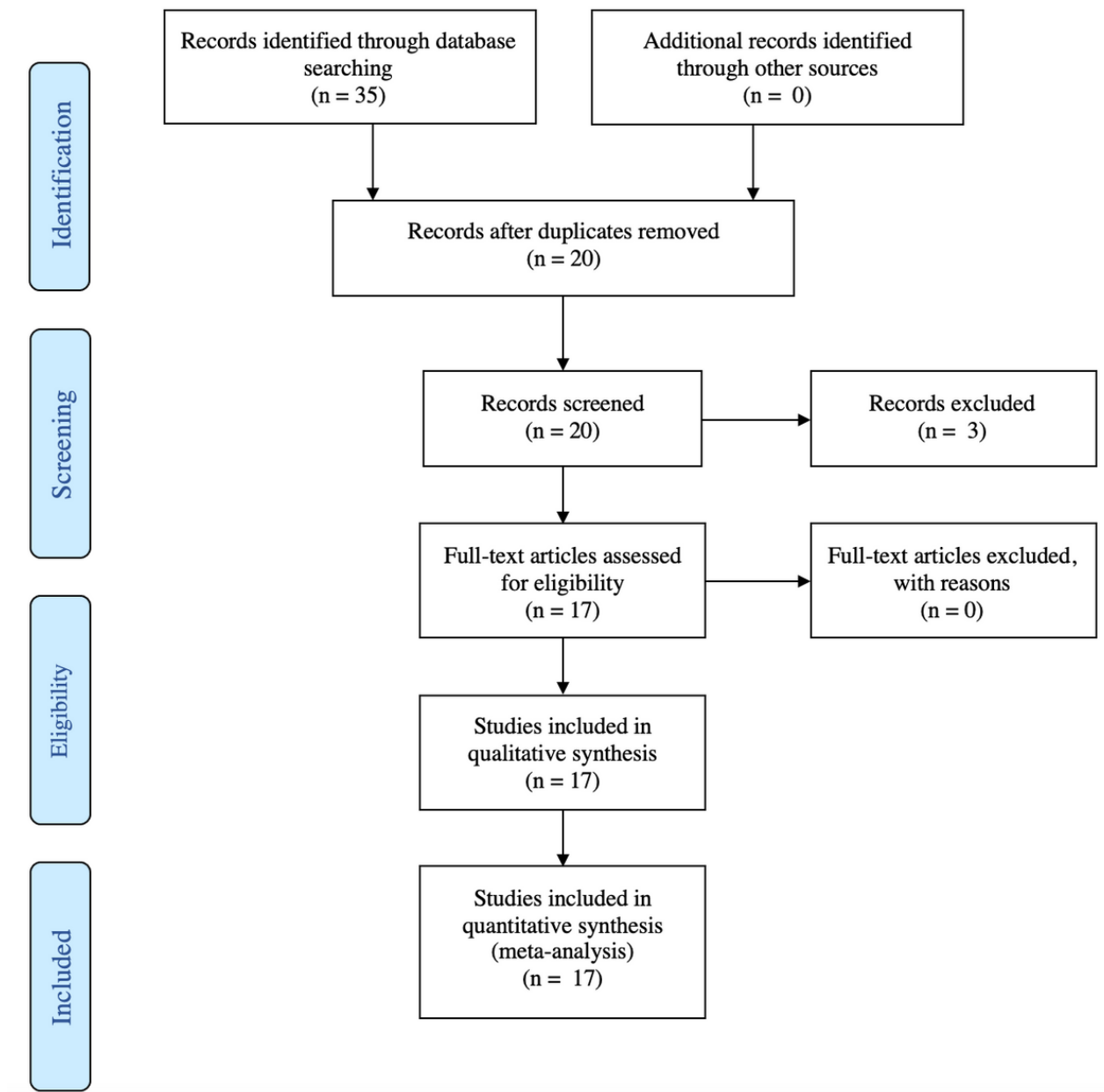


Figure 1

PRISMA Flowchart of selection process for the scoping review of DigniCap system articles/studies until May 2020