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The effect of an orally-dosed *Gynostemma pentaphyllum* extract (ActivAMP®) on body composition in overweight, adult men and women: A double-blind, randomised, placebo-controlled study

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Abstract

Background: The present study examined the effect of a herbal supplement containing a *Gynostemma pentaphyllum* (Gpp) extract (ActivAMP®) with respect to improving body composition in overweight males and females.

Methods: One-hundred and seventeen men and women aged over 18 years completed 16 weeks of daily supplementation with either Gpp or a placebo. Participants underwent dual-energy X-rays to assess body composition (fat mass, lean mass and mass distribution), as well as anthropometric measures (weight, height, hip and waist circumference), in addition to blood tests to assess inflammatory and safety markers.

Results: Following 16 weeks of treatment, the Gpp group had a significant reduction in total body weight, body mass index, total fat mass and gynoid fat mass compared to the placebo group. Blood measures showed plasma triglyceride, alanine aminotransferase and tumour necrosis factor-α to be statistically different between groups at week 16. Subgroup analysis of gender for fat distribution showed males in the Gpp group had a significant reduction in visceral fat compared to males in the placebo group and females in the Gpp group had a significant reduction in gynoid fat compared to the placebo group.

Conclusions: Gpp was capable of altering fat mass and fat distribution in overweight and obese males and females compared to a placebo.

Highlights

- *Gynostemma pentaphyllum* supplementation for 16 weeks reduced body weight and fat mass in overweight and obese males and females.
- Visceral fat reduction was observed in the male subgroup.
- Plasma triglycerides were lowered in the active treatment group.

KEYWORDS

ActivAMP®, body composition, body weight, *Gynostemma pentaphyllum*, herbal extract

INTRODUCTION

Obesity represents a major health and societal concern worldwide. Already prevalent in high-income countries, the prevalence of obesity is now increasing in low and middle-income countries, driven by multiple factors, including the post-transitional diet.[1,2] Obesity significantly increases the risk of type 2 diabetes,[3] cardiovascular disease, stroke, renal and hepatic disease, and a range of cancers.[4–6] Current interventions for obesity have poor compliance and poor efficacy as evidenced by

the growing obesity pandemic. There is a need for interventions that are effective and safe for personal use and integration into public health strategies.

Traditional treatments for obesity derived from natural compounds show great promise in the management of obesity. One such compound is *Gynostemma pentaphyllum*, a herbaceous climbing vine belonging to the Cucurbitaceae family (cucumber or gourd family).[7] This herb has been widely used in East Asian countries as a traditional herbal tea and medicine to treat obesity and diabetes,[8] amongst other diseases. Partly as a result of its documented anti-diabetic activity,[8–11] it is routinely used today in China as a treatment for hyperlipidaemia, fatty liver and obesity.[12]

The therapeutic activities of *G. pentaphyllum* are proposed to be related to the AMP-activated protein kinase (AMPK)-activating effects of the dammarane-type saponins.[13–15] The mechanism of action of dammaranes, which involves the activation (phosphorylation) of AMPK,[13–15] mimics the effects of physical exercise, including an up-regulation of autophagy[16,17] with increased mitochondrial neogenesis[18] and glucose transporter-4 expression,[19] as well as a subsequent improvement of insulin sensitivity.[20] AMPK, an intracellular energy sensor and key regulator of metabolic homeostasis, is an emerging target for metabolic diseases such as obesity and diabetes.[21] AMPK increases ATP production and decreases energy consumption by responding to cellular stress.[13] Because AMPK is activated in conditions that increase the intracellular AMP:ATP ratio, such as exercise or starvation,[22] *G. pentaphyllum* represents a potential treatment for obesity management that can complement lifestyle modifications such as exercise and diet restriction. Given the large and growing problems of overweight, physical inactivity, insulin resistance and non-alcoholic fatty liver disease (NAFLD),[16,23] *G. pentaphyllum* has a potentially important role to play in improving this key aspect of public health.

Existing safety data,[24,25] the absence of toxicity reported in clinical trials[26–28] and the growing body of evidence that *G. pentaphyllum* supports weight loss[12–14,26,27] provide a rationale for developing this traditional remedy as a public health tool in the management of overweight and obesity. Therefore, the present study aimed to assess the efficacy and safety of a commercially available capsule-form herbal supplement containing *G. pentaphyllum* extract (ActivAMP®; Gencor Lifestage Solutions) with respect to improving body composition in overweight males and females.

METHODS

A double-blind, randomised, clinical trial with a treatment duration of 16 weeks, including ActivAMP®, a commercially available capsule-form herbal supplement containing *G. pentaphyllum* ([Gpp], supplied by BTC Corporation, Korea) and placebo groups. Participants who met the preliminary screening criteria via a telephone interview underwent full screening against the inclusion and exclusion criteria (detailed below), which included collecting lifestyle, current medications and medical history. Eligible participants provided written consent for enrollment and once enrolled were randomly allocated to either the Gpp or placebo intervention group via Random Allocation Software (www.sealedenvelope.com) conducted by an individual who was not involved in the trial.

Following enrollment, participants completed baseline measures, which included body composition (height, weight, hip and waist circumference), dietary intake and quality of life. Participants were then referred to a pathology clinic to provide a blood sample and medical imaging centre for a dual-energy X-ray absorptiometry (DXA) assessment for body composition (total body fat and fat-free mass).

During the 16-week intervention trial, participants were required to attend the study clinic at weeks 5 and 10 for anthropometry assessment and to complete questionnaires. Every 2–3 weeks, participants completed 24-h diet recalls via online diaries and through telephone interviews conducted by a trial investigator. At trial completion (16 weeks), an assessment identical to that undertaken at baseline was conducted.

Participants were asked to maintain their usual level of physical activity and dietary intake for the study duration. At the end of the study, participants repeated the same exercise and diet diaries. If participants knowingly changed their normal level of physical activity or diet, they were asked to inform a trial investigator as soon as practically possible. Changes in diet and/or exercise were evaluated by a dietitian and accredited exercise physiologist respectively. Any changes to diet or exercise were taken into consideration when evaluating any results of the trial. Participants were also monitored for compliance with the protocol by email communications in addition to each scheduled site visit.

All study participants were recruited from Brisbane and surrounding areas from databases and public media outlets. The inclusion criteria included: males and females over 18 years of age who were overweight and class one obese (body mass index [BMI] > 25 to < 35 kg m^{-2}). Other inclusion criteria included not currently taking any supplements or functional foods targeted at weight loss, muscle growth or exercise performance, agreeing to not use other treatments including diets for weight loss, muscle growth or exercise performance during the study, and having the ability and willingness to participate in the study and adhere to the investigation schedule. Only females currently using an appropriate form of birth control (e.g. oral contraceptive pill) were included in the study. Participants were excluded from the study if they had any clinically significant medical condition that was uncontrolled, including, but not limited to, cardiovascular, neurological, psychiatric, renal, gastrointestinal, immunological, endocrine (including uncontrolled diabetes or thyroid disease) or haematological abnormalities. Participants were also excluded if they used prescription medication (other than the oral contraceptive pill), had significant variation in weight (more than 10%) in the past 3 months, participated in another clinical trial in the past 3 months, were allergic or hypersensitive to any of the test ingredients, consumed alcohol above two standard drinks daily, used recreational drugs or had other confounding conditions as assessed by trial investigators. Females with a clinical diagnosis of polycystic

ovarian syndrome, attempting conception or were currently pregnant or breast-feeding were excluded from the study. In total, 150 participants met the criteria and were randomly divided into two groups: Gpp ($n = 75$) or Placebo ($n = 75$).

Participants consumed 450 mg of either Gpp or a placebo with water across two capsules (225 mg per capsule) daily, one taken at breakfast and one taken at dinner for a period of 16 weeks. This regime was selected on the basis of current standard dosing guidelines for the investigational product. The placebo product consisted of maltodextrin housed in an opaque gel capsule identical to the test product.

The primary outcome was total body fat as measured by a DXA scan. Secondary outcomes included lean and fat mass distribution (from DXA), BMI, body weight, hip and waist circumferences, plasma measures (total cholesterol, triglycerides, low-density lipoprotein-cholesterol, high-density lipoprotein-cholesterol, free fatty acids, blood glucose, kidney function/safety, plasma liver function/safety, peripheral blood mononuclear cells and an inflammatory panel) and participant's quality of life [36-Item Short Form Survey (SF-36)] and dietary intake.

Sample size was calculated using G*power, version 3.0.10 (http://www.gpower.hhu.de). Accounting for an α error probability of 0.05 and powered to 0.95 for a 5% change in body composition (from baseline values; DXA; effect size $d = 0.72$), using the mean (30% body fat) and SD values (±5.5%) obtained from similar published studies, group sizes of at least 42 were required. However, allowing for an approximately 40% dropout rate, group sizes were set as 75 each ($n = 150$ total).

Data were analysed with R (R Foundation for Statistical Computing), using a range of native statistical functions and functions from the packages tidyverse, rcompanion, dplyr and ggplot. Shapiro–Wilks tested for normality of distribution, tests of significance were performed both parametrically and non-parametrically. Some variables have a log-normal distribution and were logN transformed for *t* test analysis. *p* values for *t* tests or Mann–Whitney *U* tests showing likelihood of difference between the listed Gpp and placebo were considered statistically significant at $p < 0.05$.

The trial was conducted in compliance with the current International Conference on Harmonization Guideline for Good Clinical Practice. The study protocols were approved by Bellberry Ltd Human Research and Ethics Committee (2016-11-832) and listed on the Australian and New Zealand Clinical Trial Register (ACTRN12617000839303).

RESULTS

Of the 150 participants enrolled in the study, 117 completed the study (60 for Gpp and 57 for placebo) (Figure 1). Of the 117 completed participants, full sets of DXA results were collected for 104 participants ($n = 52$ per group) and full sets of blood results were collected for 104 participants (56 for Gpp and 48 for placebo). There were no statistical differences between groups at baseline (Table 1).

After 16 weeks of treatment, the Gpp group had a significant reduction in total body weight, BMI, total fat mass and gynoid fat mass compared to the placebo group ($p < 0.05$)

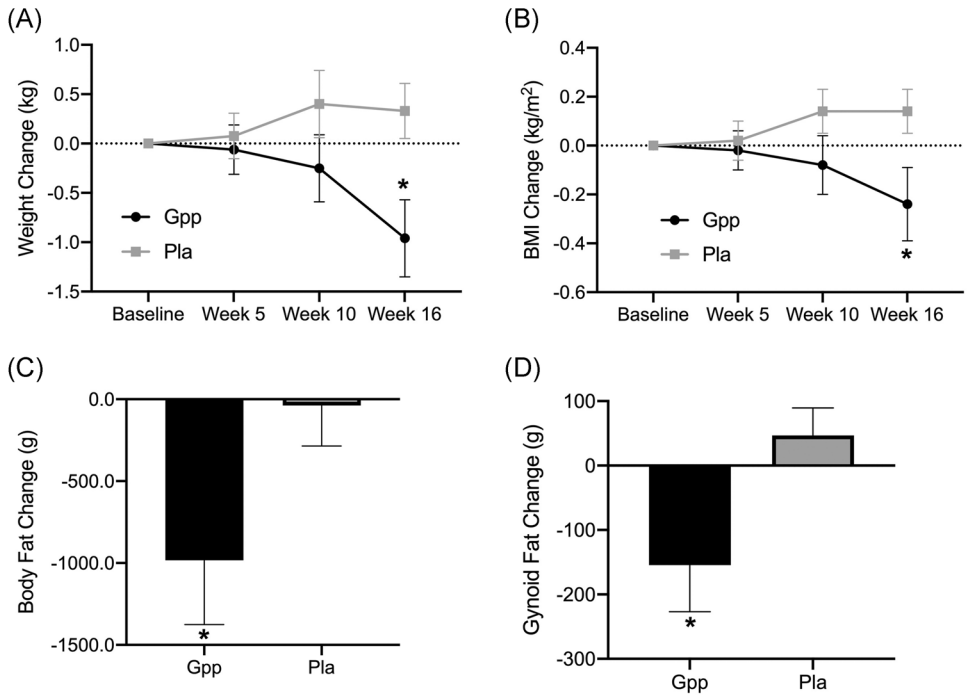

FIGURE 1 Body composition data. Body weight and dual-energy X-ray absorptiometry (52 participants per group). (A) Weight change from baseline. (B) BMI change from baseline. (C) Body fat change from baseline. (D) Gynoid fat change from baseline. BMI, body mass index; Gpp, *Gynostemma pentaphyllum*; Pla, placebo

(Figure 1 and Table 2). Percentage fat mass decreased (1.2%) in the Gpp group, which was trending toward significance ($p = 0.08$). There were no significant differences for waist or hip circumference between groups (Table 2).

There was no difference between groups for any of the blood markers at baseline. After 16 weeks of treatment, plasma triglyceride, alanine aminotransferase and tumour necrosis factor (TNF)-α were statistically different between groups ($p < 0.05$) (Table 3).

There was no significant difference at baseline or week 16 for the SF-36 health questionnaire between groups. The results indicated that all participants had good general health. Throughout the study, there was no change to any participants exercise or diet habit. Seven participants reported adverse events during the study: five in the Gpp treatment group (diarrhoea, insomnia, dizziness, nausea, dry throat) and two in the placebo group (fatigue and increased bowel movements).

Subgroup analysis of gender for android, gynoid and visceral adiposity showed males in the Gpp group had a significant reduction in visceral fat compared to males in the placebo group (−109 vs. 12 g; $p < 0.05$). Females in the Gpp group had a significant reduction in gynoid fat compared to the placebo group (−107 vs. 95 g; $p < 0.05$). No subgroup differences were seen for android fat.

TABLE 1 Participant details

	Gpp	Placebo
Randomised (*n*)	75	75
Completed (*n*)	60	57
Female (*n*)	33	30
Male (*n*)	27	27
Withdrawn (total) (*n*)	15	18
Withdrawn (did not complete baseline) (*n*)	8	10
Age mean (SD) (years)	49.4 (13.3)	50.7 (10.4)

Abbreviation: Gpp, *Gynostemma pentaphyllum*.

DISCUSSION

The present study assessed the efficacy of *G. pentaphyllum* (ActivAMP®) on body composition (including fat mass, lean mass and fat mass distribution) as measured by DXA in overweight men and women aged over 18 years of age. Secondary outcomes included BMI, body weight, hip and waist circumferences, plasma measures, quality of life (SF-36), and dietary intake.

The outcomes of this trial support earlier findings of the clinical effectiveness of *G. pentaphyllum* with respect to supporting weight loss, with good tolerability.[26–28] Furthermore, these results extend the case for *G. pentaphyllum* as an aide to weight management. Although prior work focused on the overweight (BMI < 30 kg m^{-2}) population, the present trial included class 1 obese participants.

Following 16 weeks of supplementation, the Gpp group had a significant reduction in total body weight, fat mass and BMI compared to the placebo group. Subgroup

TABLE 2 Body composition

	Baseline		Δ Week 16		
	Gpp	Placebo	Gpp	Placebo	*p* value*
Body mass (kg)	88.1 (16.7)	89.2 (13.8)	−0.96	0.31	0.02*
Lean mass (kg)	54.9 (14.5)	55.5 (12.4)	0.12	0.33	0.480
Fat mass (kg)	30.5 (6.9)	31.2 (7.5)	−0.98	−0.04	0.048*
Lean mass (%)	61.8 (7.0)	61.8 (7.6)	0.73	0.13	0.07
Fat mass (%)	35.1 (7.2)	35.3 (7.8)	−1.26	−0.10	0.09
Fat mass trunk (kg)	15.7 (3.9)	15.8 (4.6)	−0.67	−0.12	0.08
Body mass index (kg m^{-2})	29.6 (3.3)	30.4 (3.1)	−0.24	0.14	0.049*
Android mass (kg)	2.8 (0.9)	2.9 (1.0)	−0.15	−0.03	0.07
Gynoid mass (kg)	5.1 (1.5)	5.1 (1.7)	−0.16	0.05	0.03*
Android/gynoid ratio	1.1 (0.2)	1.1 (0.2)	−0.026	−0.008	0.08
Visceral fat (g)[a]	854.4 (590.0)	818.7 (597)	−36.7	7.19	0.22
Waist circumference (cm)	100.4 (11.6)	101.4 (10.1)	−0.46	−0.39	0.90
Hip circumference (cm)	113.3 (7.1)	113.0 (7.7)	−0.79	−0.48	0.30

Note: Dual-energy X-ray absorptiometry data collected for 52 participants from both groups.

Abbreviations: Gpp, *Gynostemma pentaphyllum*; Δ, change from baseline.

[a]These variables have a log-normal distribution and were logN transformed for *t*-test analysis.

*p values for likelihood of difference between the Gpp and placebo groups.

TABLE 3 Pathology results

	Baseline		Week 16		
	Gpp	Placebo	Gpp	Placebo	*p*-values
Alanine aminotransferase (U L^{-1})[a]	28.3 (15.7)	31.7 (18.1)	27.4 (11.4)	33.6 (19.2)	0.03*
Aspartate aminotransferase (U L^{-1})[b]	27.7 (9.5)	30.7 (13.8)	28.7 (8.4)	31.2 (13.0)	0.24
Gamma-glutamyl transferase (U L^{-1})[a]	30.6 (22.8)	28.6 (13.0)	29.6 (22.3)	27.7 (13.5)	0.84
Cholesterol (mmol L^{-1})	5.4 (1.0)	5.7 (1.0)	5.4 (1.1)	5.6 (1.0)	0.15
High-density lipoprotein (mmol L^{-1})[a]	1.5 (0.4)	1.6 (0.6)	1.58 (0.4)	1.60 (0.6)	0.57
Low-density lipoprotein (mmol L^{-1})	3.1 (0.9)	3.5 (0.9)	3.16 (1.0)	3.37 (1.0)	0.14
Triglycerides (mmol L^{-1})[a]	1.21 (0.8)	1.42 (0.8)	1.09 (0.5)	1.35 (0.7)	0.02*
Bilirubin (μmol L^{-1})[a]	11.3 (4.5)	12.0 (4.5)	13.1 (10.1)	11.7 (4.4)	0.56
Glucose (mmol L^{-1})[b]	5.4 (1.1)	5.3 (2.7)	5.3 (1.0)	5.3 (0.7)	0.34
Insulin (μU mL^{-1})[a]	11.3 (7.9)	10.9 (7.0)	10.6 (7.6)	11.9 (8.2)	0.24
Tumour necrosis factor-α (pg mL^{-1})	9.3 (1.5)	9.7 (2.3)	8.2 (1.7)	10.0 (2.2)	0.018*
Interleukin-10 (pg mL^{-1})	11.7 (7.6)	11.8 (8.8)	10.7 (7.1)	13.2 (7.2)	0.42
Interleukin-8 (pg mL^{-1})	24.1 (26.2)	28.2 (34.6)	23.2 (24.2)	29.5 (37.5)	0.6

Note: Pre- and post-pathology data was available for 56 participants in the Gpp group and 48 in the placebo group.
Abbreviation: Gpp, *Gynostemma pentaphyllum*.

[a]These variables have a log-normal distribution and were logN transformed for *t* test analysis; *p* values for *t* tests or Mann–Whitney *U* tests showing likelihood of difference between groups.

[b]Shapiro–Wilks distribution test found these data to be not normally distributed; tests of significance are performed non-parametrically.

*$p < 0.05$.

analysis for gender differences showed that this effect was largely a result of males having a significant reduction in visceral fat (abdominal), whereas females had a significant reduction in gynoid fat (hips and thighs), compared to the placebo group. This is plausible because males tend to carry fat predominantly around the abdominal region and females around the hips and thighs.[29,30] In the case of males especially, targeting abdominal fat may also help prevent diseases linked to a higher waist circumference.

Despite the observed reduction in body fat, there was no reduction in waist or hip circumference between groups. It may be that a greater weight loss is required to achieve sufficient change in the waist or hip circumference to achieve a significant difference. Therefore, a longer trial period in future studies may be required to see a change in these parameters. Another factor may the mixed genders in the study. With the previously discussed differences in location of fat mass loss, this would likely translate into differences in changes to waist and hip circumferences. Therefore, the males may be more likely to have a reduction in waist circumference and females a reduction in hip circumference. By conducting a mixed gender study, a possible effect on hip or waist circumference may be diluted by the opposite gender. Although subgroup analysis for gender was conducted for waist and hip circumferences, no significant changes were seen between groups. This is likely a result of the number of participants analysed in each group. Therefore, future studies wanting to look more specifically at waist and hip circumference would benefit by having power for separate groups of males and females.

Additional observations from the present study included significant reductions in TNF-α concentrations, which would be expected to confer an anti-inflammatory effect. Specifically, TNF-α levels were slightly elevated at baseline for both groups with the Gpp group returning to close to normal levels.[31] This could have been a result of the reduction in fat mass in the Gpp group because TNF-α levels correlate with BMI.[32] Adipose tissue contains a significant stromal vascular fraction, which includes numerous cell types known to produce TNF-α.[33–35] Adipose tissue in obese individuals presents with increased infiltration of macrophages,[33,34,36,37] resulting in elevated production of TNF-α.[33] Reducing the amount of adipose tissue would therefore be expected to lower TNF-α production. However, the present study was not designed to discriminate between the primary anti-inflammatory effects induced by the polyphenol constituents of the Gpp and the secondary

effects attributable to the reduction of adipose tissue. This will be a focus of future research.

Gpp may also be useful in chronic conditions where energy imbalance is centrally involved such as NAFLD, the eighth most common cause of death globally.[38] Physical exercise has been proven effective as a treatment for NAFLD,[39] with its impact mediated via the up-regulation of autophagy.[16,17,40] The ability of Gpp to induce AMP-kinase activation and therefore autophagy,[32,41] together with its anti-inflammatory effect, should be reviewed in this context. It also should be noted that, although autophagy may play a role in NAFLD, the full aetiology of NAFLD is complex and still to be established.[42] Therefore, the role of Gpp in NAFLD would need to be directly tested in NAFLD to know its efficacy.

Pre-clinical studies have already demonstrated Gpp's hepatoprotective effects in the CDDA,[43] MCD[44] and HFD[45] rodent models and there is preliminary clinical data showing that Gpp plus diet is more effective than diet alone in subjects with NAFLD.[46] This data set, together with our findings, suggests that Gpp will be a useful adjunct to physical exercise in the clinical management of NAFLD. In cases where exercise is contra-indicated or impossible, Gpp may also have value as a stand-alone in the management of this otherwise intractable condition.

In conclusion, *G. pentaphyllum* appears to be a promising compound capable of altering fat mass and fat distribution in overweight and obese males and females.

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AUTHOR CONTRIBUTIONS

Conceptualisation: Amanda Rao and David Briskey. *Methodology*, Amanda Rao and David Briskey. *Analysis*, Amanda Rao. *Writing – original draft preparation*, Paul Clayton and David Briskey. *Writing – review and editing*, Amanda Rao, Paul Clayton and David Briskey. All authors have read and agreed to the final version of the manuscript submitted for publication.

CONFLICT OF INTERESTS

The authors declare that there are no conflict of interests.

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CLINICAL PRACTICE

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Discrepancy in the evaluation of explicit and implicit nutrition care outcomes for patients at risk of malnutrition: A qualitative study

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Abstract

Background: Nutrition care plays a significant role in the prevention and treatment of malnutrition, although the challenge to establish the precise impact of a nutrition intervention on patient outcomes remains. Malnutrition can be associated with diverse underlying diseases and an increased risk of complications, which increases the difficulty of monitoring and evaluating the nutrition intervention. The aim is to gain an understanding of dietitians' reflections concerning nutrition care outcomes of interventions in patients at risk of malnutrition.

Methods: Six semi-structured audio-recorded focus group discussions with registered dietitians from primary healthcare and hospitals ($n = 29$) in Sweden were held at the dietitians' place of work or at the University. Focus group transcripts were analysed thematically to reveal patterns in the data and identify themes and subthemes.

Results: The dietitians described an approach to nutrition monitoring and evaluation of patients at risk of malnutrition that was categorised into three themes: (i) quantitative explicit outcomes, based on objective measures and described as rigorous; (ii) quantitative estimated outcomes, based on estimates and described as less rigorous and (iii) qualitative implicit outcomes, based on patients' subjective perceptions and experiences of their health and described as difficult to measure.

Conclusions: Findings indicate the need for new strategies to promote systematic and comprehensive nutrition monitoring and evaluation.

KEYWORDS

at risk of malnutrition, dietitian, monitoring and evaluation, nutrition care process, patient outcome assessment, qualitative research

Highlights

- Dietitians endeavour to quantify and measure rigorous outcomes to enable nutrition monitoring and evaluation of patients at risk of malnutrition.
- The detitians described qualitative outcomes as those often being most significant to patients.
- Qualitative outcomes were described to be less well documented in the electronic health record and therefore implicit in nutrition monitoring and evaluation.

[Correction added on 24 December 2021, after first online publication: Peer review history statement has been added.]

INTRODUCTION

Although nutrition care plays a significant role in the prevention and treatment of malnutrition[1–3], the challenge remains of establishing the precise impact of nutrition interventions on patients' outcomes[4]. It is estimated that around 50% of hospitalised patients have malnutrition[3,5,6]. Malnutrition implies risks for complications[1] leading to difficulty in evaluating nutrition interventions that require the collection of structured data[4,7]. To provide dietitians with a systematic, structured framework[8] for nutrition care, the nutrition care process (NCP) was developed by the Academy of Nutrition and Dietetics (formerly the American Dietetic Association). Over the past decade, experts from around the world have participated in reaching an international consensus about the components of the NCP model and its use as a framework[7,8]. This framework consists of four steps: (i) nutrition assessment; (ii) nutrition diagnosis; (iii) nutrition intervention and (iv) nutrition monitoring and evaluation (NM&E)[7,8]. Similar processes have been developed in other countries[9,10].

Goals are desired outcomes, agreed with the patient, that link the nutrition intervention with the outcome[11]. Goals should be SMART (specific, measurable, achievable, relevant and timely)[12]. NM&E involves Monitoring: the procedure for measuring progress and ensuring that goals and expected outcomes are realised[13] and Evaluation: the systematic comparison of current findings with previous status, intervention goals, effectiveness of care or a reference standard[5]. Evaluation also involves determining whether any changes have occurred in specific indicators. These indicators are quantitative markers that can be measured to determine the effectiveness of care[14] or outcomes directly related to the nutrition diagnosis and goals of the intervention plan[14]. During NM&E, goals will therefore be considered achieved or be modified as necessary[5].

In 2019, an NCP audit of healthcare records written by 77 dietitians revealed that goals were often not clearly documented[15]. An international survey-study (2019) investigating the implementation of NCP by clinical dietitians in 10 countries showed that the NM&E step was rarely implemented[16]. The documentation of outcomes in patients' records is essential for NM&E and continued nutrition care[13]. It may also contribute to transparency of care and promote the partnership between healthcare staff and patients[17].

Evaluation of outcomes can guide evidence-based practice[8], which forms the basis of dietitians' professional practice[18]. NM&E is important in promoting uniformity in the evaluation of the effectiveness of nutrition interventions[19]. In addition, quality of care and competence may be demonstrated through outcome management. However, there is limited research about how dietitians reflect on their practice of NM&E in patients at risk of malnutrition. Therefore, the present study aimed to gain an understanding of dietitian's reflections concerning outcomes of interventions in patients at risk of malnutrition.

METHODS

Study design

A qualitative study design was selected for this study. Focus groups with clinical dietitians were chosen as a result of their advantages in capturing the dynamic conversation between participants and gaining a deeper insight and understanding of the common experience of and reflections on the investigated topic[20–22]. Because the present study will form the basis for future interviews with patients at risk of malnutrition, patients were not involved in the research process.

Interview guide

A semi-structured interview guide was developed by the research team based on extensive discussions and literature concerning monitoring and evaluation of healthcare interventions, malnutrition risk, proposed strategies to ensure quality in qualitative research and the NCP[1–3,5,6,21,23]. The participants were asked to share thoughts and reflect upon monitoring patients at risk of malnutrition, evaluation of the nutrition treatment and measuring outcomes. Examples of interview questions included: what are your thoughts on evaluating the effect of the nutrition treatment of patients at risk of malnutrition? How would you describe a successful nutrition treatment? Do you face any difficulties in monitoring these patients? A pilot focus group with three dietitians resulted in minor revisions of the interview guide. Informative discussions emerging from the pilot focus group were also included in the final analysis. As part of a collaborative study, two focus groups included additional questions focused on NM&E of patients diagnosed with stroke and at risk of malnutrition. Data from these questions were not included in the study analysis.

Data collection

Purposive sampling was used to recruit participants[24]. The inclusion criteria were dietitians (i) with at least 1-years' experience of working with patients at risk of malnutrition and (ii) working at least 50% of full-time. Dietitians from five hospitals and three primary care settings in three regions in central Sweden were invited to participate. The dietitians worked in both high and low socio-economic status areas.

Information about the study was presented orally (SA) to dietitians at their regular meetings in the various healthcare settings to raise the issue of NM&E in malnutrition interventions and to call for study participants. Written information was emailed to those interested in participating. No information was collected regarding the dietitians who did not express interest in participating in the study. Dietitians working with diverse adult (≥18 years)

patient groups at risk of malnutrition were recruited from both primary care and hospitals to promote varied discussions. Interviews were held at the participants' workplaces for practical reasons; many dietitians in the respective focus groups therefore knew each other as colleagues.

Demographic data were collected at each interview. The sample size was guided by the analysis according to the principles of data saturation and was considered sufficient because no additional information regarding the topic emerged and no new themes were identified[25]. Studies have shown that between three and six focus groups are sufficent to cover the majority of new issues in a study[26,27].

Two of the investigators, trained in qualitative interview techniques (SA and JM), alternated roles as moderator and observer, and the interviews were audio-recorded and transcribed verbatim. The observer made notes during the interviews, which were subsequently discussed between the moderator and the observer. Most participants were not acquainted with the moderator (SA); she was introduced as a PhD student interested in developing person-centred strategies in NM&E for patients at risk of malnutrition. The interviews were transcribed by (SA, JM and a professional transcriber). None of the interviews needed to be repeated. The transcripts were not returned to participants for comments.

Data analysis

The theoretical methodology used was inductive with a critical realist approach[28]. The process of analysis was ongoing during and after the data collection and all aspects of the data were considered equally during the analysis. Thematic analysis was the process selected to analyse the verbatim transcripts. This is characterised by its methodical and interactive approach to understanding the meaning of a phenomenon within a specific context[29]. The method was used to identify, analyse and report patterns in the data in line with the six-phase guidelines initiated by Braun and Clarke[29] and with strategies proposed in qualitative research in dietetics[30]. The transcripts were read several times (SA) and discussed with all authors to minimise data selectivity[31]. Nvivo 11 (Qualitative Software for Research International) was used as a tool in the coding process and the systematic identification of themes[32]. Similar content in the data was collected in meaning units, shortened, grouped into categories and subsequently categorised into main themes by the first investigator who conducted and analysed all the interviews[29]. This step was carried out at the same time as keeping an open mind and the data were read several times (SA) and discussed with all investigators to ensure that the identified themes reflected the focus group discussions. In the final step, representative examples from each theme were extracted and discussed with all investigators in relation to the literature and the research question. As a result of extensive discussions at all stages of the analysis process, consensus was reached in the research group regarding the identified themes and subthemes. In the event of differing opinions concerning coding, the research group discussed the possible interpretations of the data until consensus was reached and everyone in the group was satisfied.

Research team

All the investigators are female and have extensive knowledge about malnutrition interventions and dietetic professional practice. Three (EL, MN and SA) are currently or were previously lecturers on a university dietetic education program. One of the investigators (YO) is responsible for the professional development of a large clinical nutrition and dietetic department. This combined experience has informed the method used in the study.

The Swedish Ethical Review Authority (Dnr 2019-02568) approved the study protocol. Oral and written information about the study purpose, voluntary participation and confidentiality was presented before each interview. Informed written consent was collected from each participant.

RESULTS

Six focus groups with registered dietitians from primary healthcare and hospitals ($n = 29$) in central Sweden were conducted in 2019 (June to December); each lasted 90–100 min. Participant characteristics are reported in Table 1. The majority of the participants were women, with around 70% of participants having a working experience of over 10 years. All had a bachelor's degree in dietetics, about one-third had completed a master's degree and one had a PhD. They all had experience of working with malnutrition interventions for patients with diverse underlying diagnoses, including chronic obstructive pulmonary disease, different cancer diagnoses, gastrointestinal diseases, and symptoms such as loss of appetite or eating difficulties that increase the risk of malnutrition. Almost half of the participants worked with either outpatients ($n = 11$) or inpatients ($n = 3$), whereas the rest ($n = 15$) worked with both.

The dietitians shared their experiences and reflections concerning NM&E of patients at risk of malnutrition. These were categorised into three themes: (1) ***quantitative explicit outcomes***, based on rigorous objective measures; (2) ***quantitative estimated outcomes***, based on less rigorous estimates; and (3) ***qualitative implicit outcomes***, based on patients' subjective perceptions and experiences of their health that are difficult to measure. The dietitians described striving to demonstrate rigorous quantitative outcomes in the electronic health record (EHR); other outcomes were less well documented in EHR and therefore implicit in NM&E.

TABLE 1 Demographics of participants (*n*) in focus group interviews with 29 dietitians discussing nutrition monitoring and evaluation of patients at risk of malnutrition

Focus group	A	B	C	D	E	F	Total
Number of participants							
	3	5	8	4	5*	5*	29
Year dietetic education completed							
1989–1999		1	2	3	2	1	8
2000–2010		2	3		4*	3*	13
2011–2018	3	2	3	1		1	8
Highest degree							
Bachelor exam	2	5	5	1	4*	4*	20
Master exam	1	0	3	3	1	1	8
PhD				1			1
Area of clinical practice							
Only outpatients	3	1		1	4	2	11
Only inpatients		1		1		1	3
Both outpatients and inpatients		3	8	2	1*	2*	15
Description of care setting and geographical area[33]							
	Primary care in a city in mid-Sweden	District hospital and primary care in a city in mid-Sweden	University hospital and District hospital in a city in mid-Sweden	University hospital in a city in mid-Sweden	District hospital & primary care in a city in mid-Sweden	District hospital & primary care in mid-Sweden	
	Population: 388,394	Population: 299,401	Population: 2,391,990	Population: 2,391,990	Population: 299,401	Population: 299,401	

*Same dietitian in two different groups.

Theme 1: Quantitative explicit outcomes

The dietitians described striving towards establishing goals that are rigorous and measurable. These were prioritised in NM&E and regularly monitored, documented and evaluated.

Explicit weight-related goals

Many dietitians stated that the main goals of nutrition intervention in patients at risk of malnutrition are either weight increase to normal body mass index (BMI) (kg m^{-2}) or weight stability.

> Unfortunately often only weight … Not only weight but that's what I write as the goal, weight stability or BMI over 22 … (Group F, person 1)

Weight was described as specific and easy to measure and therefore regularly used to determine progress in the nutrition intervention. In several focus groups, participants considered weight-related goals as one of many types of goal. However, some participants stated that weight-related goals were more often documented in EHR. In some focus groups, participants discussed a basic premise in healthcare that interventions should be measurable. They reported having been trained to use measurable and SMART goals in their dietetic education.

> We've probably been … (Group B, person 1)
>
> … influenced by NCP! (Group B, person 2)
>
> Even during my dietetic education, before the Nutrition Care Process […] we were (told) to set SMART goals, it should be measurable (Group B, person 3)

However, some dietitians were critical of this weight-centred approach and discussed the disadvantages of focusing on weight. For example, they described how assessing weight in patients with body weight fluctuations associated with fluid

balance can be difficult. In addition, evaluation based on weight changes might not reflect the patient's goals.

> Sometimes you get drawn towards setting goals that can be measured … we probably talked about something else, but I'll set this as a goal to follow up […] (Group B, person 4)

Measuring rigorous and objective outcomes

In one focus group, the dietitians expressed the desire to use laboratory values as indicators because these were considered to be measured values. However, they stressed the difficulty of using these in relation to nutrition interventions, thus making these values less valid.

> I don't know what you should set that's measurable …? You may want them to maintain their weight, and albumin and iron values, but we know that these aren't only related to nutrition (Group B, person 1)

Dietitians working in hospitals emphasised the difficulty of reaching a weight-related goal during the patient's hospital stay. Instead, regular follow-ups and sometimes life-long interventions may be necessary to reach the intervention goal.

> You can't treat malnutrition in three days … with blood sugar, you can get better control in three days, … but malnutrition can involve months of work or maybe it can never be reversed (Group D, person 1)

Although body composition was highlighted as a more reliable indicator compared to weight, many participants reported not having the equipment or routines for measuring this.

Theme 2: Quantitative estimated outcomes

The dietitians described other quantitative goals that they follow up in patients at risk of malnutrition, for example nutritional intake, food frequency and portion sizes. Outcomes related to these goals were described as less rigorous because they were based on estimates and therefore not always documented in the EHR.

Quantifying and measuring outcomes

Almost all dietitians stated that they quantify outcomes based on descriptions from patients or handover reports from healthcare staff. However, in one focus group, dietitians from primary care underlined that these are estimates rather than measurements and expressed uncertainties about the accuracy of these.

> […] how do you formulate your goals? (Group A, person 1)

> Weight if it's possible to measure, that will be a pretty important factor, especially if it's someone who is underweight …, but also what they eat and maybe how many cooked meals, variety in the food eaten … but these are estimates rather than something exact (Group A, person 2)

In another focus group, some dietitians believed that the lack of precision in such outcomes contributes to selective documentation in the EHR, with estimated values not being documented because they felt unsure of the validity of these values.

> … maybe (we should) not be afraid to estimate more, because we do estimate – eats a one-portion meal, which we know contains little protein, we estimate when we choose protein-rich oral nutritional supplements, but we maybe don't document it (Group F, person 1)

> Maybe we shouldn't be afraid to write the estimated values but we don't dare to because we haven't measured them (Group F, person 2)

Some dietitians working in hospitals described how goals are based mainly on quantitative outcomes, such as energy or food intake, regardless of the dietary advice discussed with the patient.

> … often for inpatients, I've calculated their energy requirement, and food and drink record charts have been completed, then I usually follow up how things have gone and check their weight …, they're the most common goals on the ward (Group F, person 2)

> … and what the food and drink record chart has shown (Group F, person 3)

> Regardless of what advice you've given […] (Group F, person 2)

Obtaining valid information through communication and reports

Dietitians working in hospitals discussed the need for reliable information to calculate values such as energy requirement and intake. Food and drink record charts and communication with other healthcare professionals were described as important sources of information, especially when patients are seriously ill and are unable to communicate. However, some reported that these charts were, at times, incomplete and handover reports

from other healthcare professionals or colleagues occasionally inadequate.

> […] sometimes when we get a handover report from another hospital, I'm told that the patient has eaten okay but when I ask some questions, 'but I don't really know, I haven't met the patient'. … they're handing over the care of a patient who is basically not their patient (Group B, person 4)

Some dietitians working in primary healthcare expressed uncertainty about the validity of dietary histories and highlighted the challenge of obtaining accurate and reliable information in conversations with patients, particularly if the patient has memory difficulties. Some dietitians described assessing intake of oral nutritional supplements (ONS) by comparing the patient's report of intake with the nutrition prescription. They highlighted that many times these do not correspond.

> … it's that thing with memory … it happens quite often … Maybe they say … 'I drink two ONS a day … I still have enough left' yet it was two or three months since you met them … it's not possible. You see they haven't ordered their next delivery (of ONS) … (Group A, person 3)

Theme 3: Qualitative implicit outcomes

The dietitians described establishing and monitoring qualitative goals with patients at risk of malnutrition that involve the patient's subjective experience of their health. Such outcomes were less frequently documented and evaluated.

Implicit goals of qualitative outcomes

Many dietitians agreed that including the patient's subjective experience of their health in NM&E was of enormous value. They believed that the patient's well-being and positive changes in symptoms were at least as important in NM&E as quantitative outcomes. Some stated that they usually discuss and agree on qualitative goals with patients, yet these were less frequently documented in the EHR.

> … I had a patient who wanted to go to their summer cottage, […] the goal was to make sure their nutrition care could function (there), although I might not have written that in the patient's record … but that's what it was in practice (Group D, person 2)

> Quality of life? (Group D, person 3)

> I think a lot is to do with quality of life (Group D, person 2)

Many dietitians believed that small changes can make major differences in enhancing patients' well-being, such as being able to eat in the company of other people, enjoy their food and feel less stressed about eating. These changes may improve the patient's general condition.

> I think that some people still say that they have more energy or feel stronger. Or that now I'm able to get up the stairs, I couldn't before. It's that too (Group E, person 1)

Although qualitative outcomes were less frequently documented, many dietitians described considering them in conversations with patients. Some reported monitoring these outcomes by directly asking the patients. Others stated that they could perceive improvement in the patient's condition in relation to qualitative outcomes without asking.

> When they manage to eat, I can see by looking at them that their quality of life in relation to food has improved (Group D, person 4)

Desire to focus on qualitative outcomes for comprehensive NM&E

Many dietitians conveyed a desire to focus on qualitative outcomes to enable a broader approach to NM&E. They believed that by demonstrating these outcomes the comprehensive effect of a nutrition intervention can be identified. However, participants in all focus groups stated that these outcomes are rarely measured.

> That question is always there … for my patients, they may maintain their weight [.] but … the food doesn't taste good or it's boring just sitting there …, how does it affect the way they feel, that's what you would like to find out. … you can't, there's no way of measuring that (Group C, person 1)

Several dietitians believed that measuring qualitative outcomes might not necessarily improve the quality of the nutrition intervention for the patient. Others, however, emphasised the importance of measuring diverse outcomes to ensure that relevant interventions have been selected and to promote the development of the dietetic profession.

Some highlighted the lack of validated tools to measure qualitative outcomes, while others were familiar with some instruments but had no routine for using such measurements. Several dietitians expressed frustration at not being able to demonstrate qualitative outcomes or better define nutrition-specific effects.

> … it's important that it's measurable for healthcare and the dietitian's professional role. Then I sometimes feel that it's the subjective aspects that are most important to the patient. But it's not possible to get more dietetic positions on that basis. That my patients feel better after seeing me. […] and if the intervention doesn't give any improvement you have to maybe try something else. So that's why it's important to have something you can measure (Group C, person 2)

Some underlined the difficulty of measuring and evaluating the contribution of the dietetic profession to healthcare.

> … there is no easy tool for measuring what we do. […] It would be great …, but there isn't because it depends on so much else. … it may be that the patient was given a new medication that increased their appetite. Did I do something or is it to do with the patient … It's really difficult. So it's quite unique for our profession that it's very difficult to measure (Group C, person 3)

DISCUSSION

The present study aimed to investigate dietitian's reflections concerning outcomes of interventions in patients at risk of malnutrition. By highlighting dietitian's reflections, new strategies corresponding to dietitians' requirements and the capacity for NM&E can be proposed for future development and the implementation of this step of the NCP. The findings highlight that dietitians endeavour to quantify and measure rigorous outcomes to enable NM&E of patients at risk of malnutrition. Meanwhile, the dietitians described the nutrition intervention as being characterised by qualitative outcomes. Although critical of the weight-centred focus in NM&E described, they maintained that this was the most practical and most 'measurable outcome'. However, malnutrition requires long-term[34] and, according to the participants, sometimes lifelong interventions, making it difficult to reach the intervention goal, especially during a hospital stay. BMI as a concept has been criticised in the literature because of its lack of accuracy in mapping weight to health risk for individuals[35,36]. Relying on a measure that fails to acknowledge psychological as well as physiological dimensions of health has been described as limiting the ability of clinicians to appreciate the relationship between these dimensions[36]. Hence, focusing on weight or BMI in NM&E may not reflect short-term outcomes of the nutrition intervention. Importantly, if relevant and short-term outcomes other than weight-related outcomes are not clearly documented, there is no opportunity to determine the effects of the nutrition intervention[37].

The NCP includes a diverse range of NM&E terms[14] that could be used to complement the weight-centred approach described in this study, for example terms associated with qualitative aspects such as '*Ability to build and utilize social network*' or '*Nutrition Quality of Life*'[14]. However, as also discussed in previous research, dietitians tend to associate the NCP with quantitative outcomes[38]. Some dietitians reported being trained in quantifying and establishing SMART goals [12]. This may reflect the Swedish dietetic education[39] because the participants highlighted that they were 'trained' in quantifying. The participants also reported emphasising quantitative outcomes in their documentation. However, if outcomes related to qualitative aspects are not documented, there is a risk of losing vital information that is important in the continuity of care[5].

Participants also described qualitative outcomes as those often being most significant to patients. In person-centred care, the EHR acts as a contract between patients and the healthcare staff whereby patients have access to the documentation in the EHR[17]. Hence, emphasising patients' priorities and goals through documenting qualitative outcomes in the EHR is of huge importance in enabling person-centred care and comprehensive NM&E. To provide patient-safe, person-centred care, all aspects of relevance and importance to patients should therefore be addressed in the process of NM&E.

Although qualitative outcomes were not documented explicitly, the dietitians discussed how, in practice, they rely on their clinical judgment to monitor these outcomes. A significant aspect of a professional's clinical judgment is intuition, defined as a response without rational calculation[40]. Intuition develops through experience and constitutes a substantial part of the everyday practice of experts[40]. The dietitians described how they could sense if goals corresponded to the patient's needs and if the patient's condition was improving; however, this involves tacit knowledge that is difficult to verbalise and demonstrate in NM&E. Tacit knowledge is intuitive and is unconscious knowledge gained from experience[41]. Explicit knowledge, on the other hand, involves rules, facts and policies that can be documented and shared without question[41]. The findings in the present study highlight the gap between the tacit knowledge informing the dietitians' practice and the explicit knowledge that the dietitians are keen to demonstrate.

There is evidence concerning the role nutrition plays in aspects of a patient's life such as in well-being, quality of life and general health[42,43]. Most participants underlined the significance of these in NM&E for both the benefit of patients and the development of the dietetic profession. Some participants suggested that qualitative outcomes could be evaluated and made explicit through the use of validated nutrition-specific tools. There is presently a lack of validated patient-reported outcome measures (PROM) for the evaluation of nutrition-specific effects[44]. PROM are validated instruments that measure patients' self-perceived health, function and health-related quality of life[44]. They enable identification of aspects of importance for patients' well-being that can be either impaired or improved

during the course of the intervention. However, PROM may not capture all aspects of a patient's complex situation; the qualitative conversation and the patient's stories will most often achieve a deeper dimension than can be reached using instruments such as PROM. For patients at risk of malnutrition, however, PROM may fill the gap between the explicit and implicit aspects of NM&E. Furthermore, as also suggested in previous research, there is a need to perform a broader and more comprehensive NM&E in the NCP[45]. This could be realised through highlighting existing qualitative elements in the process during dietetic education and in the implementation of the NCP. Likewise, a more comprehensive NM&E could also be promoted by developing the NCP through the addition of further important qualitative aspects.

Strengths and limitations

A strength of the present study is that the participants were recruited from different settings and work with patients at risk of malnutrition with diverse diagnoses, which promoted valuable discussions. However, the discussions reflected participants' perceptions and views, and should not be interpreted as characterising how they actually practice NM&E. An additional strength is that all authors have clinical experience of working with patients with malnutrition, have been involved in the entire analysis process and have experience of qualitative methods.

The data selection was limited to a concentrated geographical area, which is acceptable when using a qualitative approach. However, including participants from different regions in Sweden and complementing the data with patient interviews may have provided more insights into the topic.

Although we tried to obtain heterogeneous groups to stimulate interesting discussions, many dietitians wanted to be interviewed in their own healthcare setting for practical reasons. Many dietitians in the respective focus group therefore knew each other. However, they stated that they had not discussed the topic previously and that the focus group had given them new insights and reflections. The approach used in the present study was broad, involving dietitians working with outpatients and inpatients at risk of malnutrition with diverse diagnoses and needs. Further questions regarding differences in the practice of NM&E in these diverse settings would have promoted interesting discussions. We suggest therefore that additional research investigating these differences should be undertaken. We also propose new studies focusing on specific groups of patients who are at risk of malnutrition to identify particular aspects concerning these patients.

CONCLUSIONS

Our findings highlight a gap in NM&E because the dietitians described qualitative outcomes as being most important to patients yet these were implicit in NM&E. Instead, they described striving towards explicit quantitative outcomes to enable the process of NM&E. We stress that the specification of patients' perspectives in NM&E is necessary to promote person-centeredness, improve communication between patient and healthcare provider throughout the chain of care, and support evidence-informed practice of dietetic interventions. Hence, new strategies to elucidate patient's goals and priorities through a more comprehensive NM&E are required. By involving patients in setting goals, aspects of importance to patients can be followed up and evaluated. We suggest an investigation into how patients at risk of malnutrition reflect on NM&E to highlight their needs and improve NM&E practices among dietitians.

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CONFLICT OF INTERESTS

The authors have no conflicts of interest.

AUTHOR CONTRIBUTIONS

All authors participated in the conception and design of the study, as well as the analysis and interpretation of the data. Lina Al-Adili and Jenny McGreevy performed the data collection. Lina Al-Adili was responsible for drafting the manuscript. All authors contributed with critical revisions and supervision.

ETHICAL APPROVAL

Ethical approval was obtained from the Swedish Ethical Review Authority (Dnr 2019-02568).

TRANSPARENCY DECLARATION

The lead author affirms that this manuscript is an honest, accurate and transparent account of the study being reported. The reporting of this work is compliant with COREQ guidelines. The lead author affirms that no important aspects of the study have been omitted and that any discrepancies from the study as planned have been explained.

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PEER REVIEW

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SUPPORTING INFORMATION

Additional Supporting Information may be found online in the supporting information tab for this article.

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