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A Qualitative Evaluation of patients' experiences of a Psychoeducational Programme to Restore Hypoglycaemia Awareness

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Title: A qualitative evaluation of DAFNE-HART: A psychoeducational programme to restore hypoglycaemia awareness.

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Abstract: Aims: Impaired awareness of hypoglycaemia (IAH) in people with type 1 diabetes is a dangerous condition that is associated with a six-fold greater risk of severe hypoglycaemia. A new psychoeducational programme, DAFNE-HART, has been specifically designed to address persistent IAH. The initial pilot showed promising outcomes including fewer hypoglycaemic episodes and improved hypoglycaemia awareness. This aim of this paper is to describe the development and qualitative evaluation of DAFNE-HART from participant interviews.Methods: DAFNE-HART incorporates diabetes education with two psychological approaches that have demonstrated efficacy in long-term health conditions: motivational interviewing and cognitive behaviour therapy. The course, delivered across two UK locations included both group and individual support over a six-week period facilitated by DAFNE educators, trained and supervised by a clinical psychologist. Semi-structured interviews were conducted with 19 participants immediately after their courses and the interviews were analysed using grounded theory.Results: Five main themes emerged which describe the behavioural changes people made to their diabetes management, the development of new attitudes and beliefs, their experiences of regaining hypoglycaemia cues, reactions to the course format and the significance of the relationship with their care provider. Participants provide insights into how the course changed their view of IAH and led to practical changes in minimising hypoglycaemia.Conclusions: Integration of psychological techniques into diabetes education can address the cognitive and motivational barriers to restoring awareness and optimal diabetes management. It is suggested that further research is needed to evaluate this programme in a larger sample and to measure sustainability.

Dr Emma Shuttlewood Clinical Health Psychology Clarence Wing St. Mary's Hospital Praed Street London W2 1NY

1st October 2014

Dear Diabetes Research and Clinical Practice,

Please accept a submission for the following paper to be considered for publication:

A qualitative evaluation of DAFNE-HART: A psychoeducational programme to restore hypoglycaemia awareness

This paper has been written and edited by Shuttlewood, De Zoysa, Rankin and Amiel. I, the corresponding author, have now left the department at King's College London but am happy to be contacted about his paper.

I look forward to hearing the reviewer's comments.

Yours faithfully,

Dr Emma Shuttlewood.

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Conflict of Interest.

We wish to confirm that there are no known conflicts of interest associated with this publication and there has been no significant financial support for this work that could have influenced its outcome.

Abstract.

Aims: Impaired awareness of hypoglycaemia (IAH) in people with type 1 diabetes is a dangerous condition that is associated with a six-fold greater risk of severe hypoglycaemia. A new psychoeducational programme, DAFNE-HART, has been specifically designed to address persistent IAH. The initial pilot showed promising outcomes including fewer hypoglycaemic episodes and improved hypoglycaemia awareness. This aim of this paper is to describe the development and qualitative evaluation of DAFNE-HART from participant interviews.

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Conclusions: Integration of psychological techniques into diabetes education can address the cognitive and motivational barriers to restoring awareness and optimal diabetes management. It is suggested that further research is needed to evaluate this programme in a larger sample and to measure sustainability.

Keywords: Hypoglycaemia, Type 1 diabetes, Psychoeducation, Motivational Interviewing, Cognitive Behaviour Therapy, Qualitative.

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1. Introduction

The medical management of diabetes is complicated by the occurrence of hypoglycaemia (low blood glucose concentration) which can be severe enough to cause confusion, abnormal behaviour, seizure, coma and, in rare cases, death [1,2]. Such severe hypoglycaemia is particularly a problem for a subset of people with impaired awareness of hypoglycaemia (IAH). This means they have lost their protective counter-regulatory responses that would normally defend against hypoglycaemia. Consequently, people with IAH do not experience the early warning signs of hypoglycaemia (e.g. hunger, dizziness, sweating) which usually prompt the protective action of glucose ingestion to raise blood glucose concentration.

In adults with type 1 diabetes, IAH increases the risk of severe hypoglycaemia, defined as that requiring external assistance, up to six fold [3] and affects 25-40% of the population [3,4]. Furthermore, IAH has been found to increase the risk of severe hypoglycaemia up to seventeen fold in people with insulin treated type 2 diabetes [5]. Recent qualitative analyses of the experiences of IAH amongst patients and their family provide insights into the on-going anxiety present when people are unable to detect dangerously low glucose concentrations [6,7]. IAH can develop when people have been repeatedly exposed to hypoglycaemia without corrective action [8]. However, research studies [e.g. 9] have demonstrated that IAH can be reversed by strict avoidance of hypoglycaemia through behavioural means i.e. making medication and dietary changes to reduce the frequency of hypoglycaemia and treating any episodes promptly.

Dose Adjustment for Normal Eating (DAFNE) [10] is a well-established example of an international structured education programme for adults with type 1 diabetes. DAFNE promotes flexible insulin therapy and has demonstrated improved glycaemic control, reduced rates of severe hypoglycaemia and improved perceived well-being at one-year follow up [4]. Nevertheless, a significant proportion of people with IAH (approximately 50%) continue to have impaired awareness after attending a DAFNE course. A number of other programmes specifically targeting problematic hypoglycaemia, such as Blood Glucose Awareness Training (BGAT) [11] and Hypoglycaemia Anticipation, Awareness and Treatment Training (HAART) [12], have demonstrated beneficial outcomes but have also failed completely to restore awareness or prevent severe hypoglycaemia. A group of people with type 1 diabetes thus continue to experience problematic hypoglycaemia that is resistant to conventional educational interventions.

Various studies have explored the barriers that might prevent people from taking the necessary action to reduce IAH and severe hypoglycaemia. Neuroimaging studies have demonstrated reduced stress responses and failure to deactivate reward/pleasure pathways during hypoglycaemia in people with IAH compared to those with intact awareness [13]. Such responses are compatible with de-sensitisation to the stressor and may be expected to reduce subjective awareness of the dangers of each event and impact upon the motivation to avoid subsequent ones. In relation to this, a clinical audit demonstrated that patent with IAH were less adherent to recommended treatment regimen changes than people with intact awareness [14]. A qualitative study categorised a subset of patients with IAH as having "low concern" about their condition and identified a number of unhelpful beliefs that might reduce people's motivation to address this [15]. These included normalising IAH as being a natural part of diabetes, underestimating the consequences of persistent IAH, a fear of attracting attention or being seen as abnormal by testing for or treating hypoglycaemia and overestimating the

impact of episodic high glucose readings. Furthermore, these findings, and the outcomes from structured education programmes to date, imply that education alone is not sufficient to restore awareness and that psychological factors, such as individual perceptions of IAH and motivation also need to be addressed. This rationale informed the development of a new psychoeducational intervention called DAFNE-HART.

DAFNE-HART stands for Hypoglycaemia Awareness Restoration Therapy and was designed for people who had previously attended DAFNE and still had persistent IAH. Like DAFNE, DAFNE-HART was based upon social learning theory (SLT) [16], patient empowerment and increasing self-efficacy via experiential learning. Thus the programme was run primarily in a group format, revised DAFNE principles in relation to hypoglycaemia and encouraged participants to try out new behaviours and report back via blood glucose diaries and group discussion. The innovation in DAFNE-HART was to include principles of Motivational Interviewing (MI) [17] and components of Cognitive Behavioural Therapy (CBT) [18]. The inclusion of these two psychological approaches was to address the motivational and perceptual barriers to restoring awareness in people with IAH.

The MI approach has been found to be more effective than traditional advice giving in a range of behavioural problems and long term conditions, including diabetes [19]. In DAFNE-HART the spirit or attitudinal stance of MI (evocative, collaborative, emphasising patient autonomy) was woven into the style of facilitation. This was to minimise defensiveness and increase motivation to address hypoglycaemia risk factors. Health information was offered via an 'elicit-provide-elicit' model [20] whereby information was first elicited from the group, before new information was offered and then checked back. CBT can address unhelpful cognitions and improve adjustment to a diabetes diagnosis and self-management behaviours [21]. The CBT component of DAFNE-HART provided education regarding the link between thoughts, feelings and behaviour around hypoglycaemia and supported problem solving and relapse prevention. It used questionnaires and discussion to support patients to identify unhelpful thoughts regarding hypoglycaemia and to restructure these thoughts via Socratic questioning and reflective writing.

A pilot study of the DAFNE-HART course found significant reductions in severe hypoglycaemia, increased subjective awareness of hypoglycaemia symptoms, and reduced worry and unhelpful behaviour around hyperglycaemia at 12 month follow up [22]. This research explores the patients' experience of participating in DAFNE-HART, their reactions to the course content and structure and its impact upon their perceptions and management of hypoglycaemia. The aim of this research was to understand how participation in the course led to improved outcomes and how to refine the course for future use based on patient feedback.

2. Methods

2.1 Intervention

DAFNE-HART was developed by a clinical psychologist with diabetes experience (NdZ), collaboratively with diabetes physicians, DAFNE educators and DAFNE users. The course ran over six weeks: weeks 1-3 were three full day group sessions, weeks 4-5 were individual face-to-face and phone appointments and week 6 was a full day session with an invitation for a significant other to join the session. An overview of the programme is detailed in Appendix 1.

In weeks 1 and 2, participants revised the risk factors for hypoglycaemia and were taught a focused attention technique (the 'Body-Senses-Mind' [BSM] scan) to help them identify novel cues of hypoglycaemia that may have previously gone unnoticed. In week 3, common psychological barriers preventing hypoglycaemia avoidance were introduced as 'thinking traps'. For example, the 'sergeant major' thinking trap which prevented people from stopping to treat hypoglycaemia due to 'soldiering on' despite a low blood sugar. Managing hypoglycaemia in a social context was also discussed with strategies to manage this. In weeks 4 and 5, participants had an opportunity to try out their new skills/strategies. Week 6 focused on relapse prevention and support for significant others.

To accompany the programme, visual aids were developed to highlight key teaching points and participants received a workbook, including a personalised 'hypo prevention plan'. Five DAFNE educators from two DAFNE centres attended a two-day workshop with the clinical psychologist (NdZ) to learn skills in MI and the CBT theory relating to hypoglycaemia avoidance. Psychological supervision was provided weekly throughout the course.

2.2 Sample and recruitment

Twenty-four adults with Type 1 diabetes and current problematic hypoglycaemia, defined by a Gold score [23] of 4 or more, were recruited from two UK DAFNE centres. Two groups ran in each centre, run by two educators trained as above. Participants who agreed to undertake DAFNE-HART also agreed to take part in a post-course interview to discuss their experiences and were informed that their feedback would be anonymised.

2.3 Data collection

In-depth interviews with participants were conducted by an experienced researcher (DR) immediately after completing the six-week course. Interviews were undertaken by telephone at a time convenient for participants, digitally recorded with consent, and transcribed in full to allow for detailed analysis. Topic guides were developed in light of the study's research questions and literature reviews and revised in light of findings emerging from concurrent data analysis, in line with the principles of grounded theory research [24]. Key areas explored included: participants' reasons for agreeing to attend the course, how they felt about the group format, what aspects they liked or disliked, how they thought the course could be improved and the perceived impact the course had on their attitudes towards and experiences of preventing and managing hypoglycaemia.

2.4 Data analysis

Interviews were entered in NVivo data management programme (QSR N6, QSR International, Doncaster, Australia), and an initial coding frame developed to capture data relevant to the study's key research questions. The coded datasets were analysed using content and inductive thematic analysis by a researcher independent of the development and delivery of the programme (ES). Each transcript was read through several times to produce an initial description of the patterns in people's experiences, i.e. the semantic themes. These were further organised into hierarchical themes, highlighting where experiences clustered and where they diverged.

Research ethics approval was granted by the National Research Ethics Service, King's College Hospital Research Ethics Committee (05/H0808/53) and all participants gave written informed consent.

3. Results

A total of 21 out of the 24 participants were available for interview, although data saturation was reached after 19 interviews were analysed. There were nine female participants (47.4%), with a mean age (\pm SD) of 53.3. \pm 8.1 years, and years since diagnosis 31.2 \pm 11.3 years.

A total of five themes were identified in the data which highlight the impact of the course including the changes the participants made to their diabetes care, the development of new cognitions, as well as how the course was experienced in terms of the structure and format and relationships with care providers. The themes are described in detail below.

3.1 Changes in diabetes management

Patients reported a range of behavioural changes following course attendance which included increased monitoring of symptoms and behaviour, using more effective hypoglycaemia treatment and carrying the necessary treatment with them. For example:

"...now I carry a kit around with me. It's got energy bars in if I'm going to be away from food for a while but I'm not that low, I have orange juice for the quick acting treatment. I keep a full kit with me now which I've never done" (16, R3).

"I always used to have, have a glass of milk ... but, now, since going on the course, I have fruit juice or jelly babies" (04, R1).

Post-course, most (10 of 19) also reported testing their blood glucose more regularly, looking for patterns in blood glucose readings and retesting shortly after a low value. As a result of increased monitoring, several patients reported having identified particular times or contexts in which hypoglycaemia tended to occur and how this had enabled them to take preventive action:

"... one of the useful things about the past few weeks has been, well, you know, if that's when they're happening, then if I test mid-way, I can see which direction they're going in....So, I've saved, I reckon I've prevented, ooooh probably about four hypos a week" (01, R1).

In addition, many people (11 of 19) described making more accurate adjustments to their insulin, having stopped over-correcting for high glucose levels and treating low blood glucose levels more quickly. For example:

"...[I] took the compensating injections out because I were compensating for some'at [something], really, that I shouldn't be compensating for" (09, R7).

"...but I've learnt that ... if I am three point four or something like that, to actually treat it as a hypo which I never used to do" (10, R4).

"...sort of get it into me head it's, treat it, don't wait to treat it thing" (07, R1).

Some participants (8 of 19) described practical ways to integrate the knowledge from the course into their daily lives in order to sustain efforts to maintain awareness:

"...I've stuck a notice up on the notice board, saying, are you shaking, can you recite, you know, some phone numbers, can you, 'cause I make costumes, can you thread a needle? If you can't, go and get some orange juice" (17, R5).

"...I've set my alarm on my phone so once a week it's gonna come up and say, just spend half an hour reading through some of this stuff..." (12, R1).

3.2 Regaining cues

The majority of participants (15 of 19) commented that being encouraged to set aside time to look for novel cues had been effective in regaining awareness:

"..the idea of looking for specific signs and symptoms I think is useful as well because, probably something that's been mentioned before, you know, it seems a fairly obvious thing to mention but, actually, looking at it in such detail makes it a lot easier to practice" (03, R3).

"Since doing the HART course I've rethought every, you know, before I do me blood sugars now I sit there and think am I shaky, am I hot, am I sweating, can I feel me feet, can I feel me legs, I do that nearly every time" (13, R2).

"I find it very hard to sit relax, you know, relax and think and I, I thought this is daft but it does work" (09, R2, participant describes attempting the BSM scan).

Some participants (5 of 19) highlighted how, as a result of attending the course, they detected low blood glucose concentrations sooner than before, for example:

"..when I had these very, very, very vague symptoms like maybe a very slight headache or, abdo [abdomen] discomfort or something like that, it would invariably be about one point three. Now, if I'm, if I feel anything at all, it's often above here which I actually see as a positive" (02, R7).

"..it's great I'm picking them up around about four, three point eight...that's the first time for ages," (11, R3).

However, not all of the participants found this helpful and a few (3 of 19) said that they did not experience any benefits from trying to identify possible cues or estimate their blood glucose levels. Some confusion was expressed regarding when to stop and look for cues versus treating a low glucose level, for example:

"... I must admit a lot of us were a little confused by, and I was one of them, we were actually doing performance cues and body scans when we were too low, instead of getting up and treating the hypo" (16, R7).

3.3 New diabetes-related cognitions

Participant comments appeared to reflect a sense of hope or renewed belief that restoration of awareness was possible, such as:

"..I'll keep trying now I know that there is a way of getting your warning signs back. That's what I'm heading for, that door, I know it might take a long time but I know that it's possible now" (13, R9).

In addition to this, participants highlighted an increased sense of determination to restore awareness and a perceived need to be *"proactive"* (03, R3) in this:

"...it is mine and I've got to learn to live with it, I've got to sort it out, nobody else can do it but me" (15, R2).

Over half the participants (10 of 19) described greater control and confidence in their diabetes management:

"... I suppose having the confidence to think, oh I'm high but don't worry about it, it will adjust itself, so long as I get the overall, long term insulin right and adjustment dose right, don't worry about too high, for a period of time, it will come down, eventually" (06, R3).

"...I'm more relaxed about letting it, letting my glucose run a bit high after meals" (17, R3).

The majority of participants (14 of 19) directly commented on how the 'thinking traps' concept had helped them become aware of their unhelpful thoughts and the detrimental impact it can have on their diabetes management such as preventing them testing, delaying hypoglycaemia treatment and feeling unwell for longer. For example:

"It's, that's me whole problem, I think it's, I'll sort it in a minute 'cause I'm telling meself it's not, oh, it'll be alright, oh, I've got plenty of time" (07, R2).

"...as we've learnt from this course a bit of a 'sergeant major' and I don't like people to see me, not, well yeah in a vulnerable position, even family and friends and that" (16, R1).

Many participants (9 of 19) reported a *"different way of thinking"* (15, R2) towards their hypoglycaemia management, enabling them to be less self-critical and anxious. This was important as it reduced the levels of blame and anxiety around issues of self-management.

"But I think me initial thoughts when we started the course is well actually it's my fault because I'm not taking any notice and basically it is but in a nice way. So they made you rethink your own mind set about, you know, what you were doing and why you were doing it and help you get over that" (16, R5).

Overall participants expressed positive views about the facilitation style and psychological material within the programme, specifically regarding the thinking traps and BSM scan. The type of comments people made included words such as 'useful', 'clever' and 'interesting'. This extended to people who initially reported being sceptical about the psychological approach used in the course:

"The thinking traps were really interesting, actually, because when I first did the thinking traps, I thought, ah well, you know, these are gross generalisations that, you know, I'm not really, I'm already over all of these things 'cause these were things that I sort of, you know, felt before but I don't feel those now because I've got used it all and I'm fine and, of course, the more we talked, you know, the more I sort of, you know, thought about them and I thought, well, actually no, I do all of those things, you know, absolutely every single one of them" (11, R3).

3.4 Reactions to the format and structure

The majority of the participants (14 of 19) reported that the group setting facilitated their learning and understanding. Participants described how being in a group of people with similar experiences provided insights into their own behaviour and prompted them to make changes, for example:

"...listening to other people's experience and thinking, now what would I do in that situation has, has caused me to sort of reflect, well yeah, not what I would do in their situation but just have a look at some of my own experiences and is there anything I can do to change it" (01, R3).

"..one of the guys was talking about plastering and he would just want to plaster the wall and he just like keep going, even when he was about to fall off a ladder and I can really, that really resonated for me" (11, R3).

"... I mean one of the reasons I keep a kit now is because every single person I was on the course with had a kit and it were seeing them with their kits that made me realise I'm the only one that don't do this" (16, R6).

The group setting also provided a sense of a wider community and making connections with others, including swapping contact details.

In addition to the benefits for the individuals, a couple of participants commented on how the group setting was helpful for their family members who attended one of the sessions. For some individuals meeting people who were perceived as less fortunate than themselves, helped put their own situation into context.

Some people (5 of 19) found the group setting challenging because they did not have anyone they could identify with, felt less confident or found other members of the group to be more challenging. Furthermore, many participants (15 of 19) found the one to one sessions as well as the group format valuable. Participants appreciated the individual attention and felt it was easier to be more open:

"I think you can say things in a one-to-one session which I would never dream of saying in a group session and so from that point of view, very much valued" (01, R3).

"...it's very hard, in a group, to be able to say look I don't understand that" (11, R3).

Most participants (10 of 19) seemed to find the structure of the course helpful as it provided them with a reflective space to consider alternative perspectives and try out new behavioural strategies, for example:

"I think with this course, it's trying to make you think about stuff more because there is no magic remedy and it's, kind of, down to you as individuals to think about things and maybe see if that'll work for you and if they, sort of squash it all down into a week, you wouldn't actually have that, that thought time to come" (02, R4).

"... it gives you a chance to sort of go away and reflect, try things, come back and, and question" (12, R1).

3.5 Relationship with care provider

A common theme which emerged from the interviews was the relationship and 'trust' between the patient and care provider. A few participants (4 of 19) cited this as a motivation for participating in the study and reported wanting to participate to 'pay back' the organisation to ensure the relationship continues, such as:

"I want to remain with [Location] and I felt, when they asked me to go on it, I felt that it would be a good idea and they'd carry on looking after me. That, that is true, I mean, I would never say that to [Educator] but that is truly the reason why I, I agreed to" (02, R3).

Once enrolled in the study, many participants (10 of 19) remarked on how the facilitators created a *"supportive and nurturing environment"* (06, R3) through their *"non-judgemental"* approach (12, R1) and appeared credible and informed. For example:

"Clearly, incredibly knowledgeable, if you come across something where they don't know, they'll say they won't know which means that you believe what they do say they know" (12, R1).

"..she gave me encouragement to carry on with what I was doing even though these warning signs are not bouncing out at me yet and it was nice to know" (15, R2).

"..that was the point for me, that there was people who understood, trying to help you to grapple with your own individual problems" (05, R4).

Several participants (6 of 19) also commented upon the facilitative and empowering response style of the Educators. For example,

"..it did help a lot of the time for her to say so what do you think you should be doing, you know, making me think about it rather than me expecting somebody else to be able to tell me what to do" (15, R2).

"...she's waited for me to see it myself and I find that's always good because it's always easier to spot it yourself than have somebody point it out to you ain't it?" (16, R7).

4. Discussion

This qualitative study describes the participant experience of DAFNE-HART, a pilot psychoeducational course targeting persistent IAH in people with type 1 diabetes. It provides a useful context from which to interpret the quantitative findings, which included significantly fewer severe and moderate hypoglycaemic episodes and improvements in hypoglycaemia awareness without deterioration in overall glycaemic control 12 months after course completion [22]. In this qualitative study, participants reported behavioural changes in their diabetes management which would be expected to reduce or minimise their experience of hypoglycaemia, giving them an opportunity to regain their subjective awareness of low blood glucose. Self-management strategies reported after the course included increased monitoring of cues, more accurate corrections and adjustments to insulin, increased testing and use of more effective and readily available hypoglycaemia treatment. It is important to note that many of these strategies would have already been discussed with these patients, either through DAFNE or during individual consultations and yet not been translated into sustainable action. Below we consider why this group of patients, were able to make these changes more successfully, after attending the course. The Self-Regulation Theory [25] suggests that the cognitive 'representations' people have of their health condition in terms of identity, consequences, timeline, cause and controllability influence their subsequent behaviour. The DAFNE-HART programme aimed to change people's perception of threat and the behavioural causes/consequences of IAH and foster resources to cope and better self-manage. Evidence from this pilot study suggests that patients created a new illness template around IAH; acknowledging a level of personal agency in disrupting the vicious cycle of impaired awareness. This may have enabled people to challenge previously held ideas that IAH was an inevitable or irreversible condition [6]. In addition, the sense of control and empowerment described by many in this study fits with previous findings that beliefs around, and perceived control of, diabetes is a significant predictor of engagement in health behaviours [26].

DAFNE-HART also included techniques from CBT. There is evidence for CBT's effectiveness in improving diabetes control [e.g. 27,28] but this is the first attempt to use the approach to address persistent problematic hypoglycaemia. Importance has been placed on adapting CBT to the needs of the specific population [29], and the DAFNE-HART programme focused upon the negative automatic thoughts related to IAH and its role in maintaining behavioural avoidance. In this study, patients reported an increased awareness of the unhelpful thoughts which may have prevented them treating or reducing the frequency of hypoglycaemia. For example, the need to 'soldier on' and not be perceived as causing a fuss by stopping to test blood glucose or treat an episode. Participants reported alternative perspectives e.g. more accepting of intermittent hyperglycaemia and developing new beliefs around their hypoglycaemia management such as treat now and don't delay. Hence, the CBT component of DAFNE-HART may have enabled participants to address some of the cognitive barriers preventing them making optimal use of previous education.

The relationship people have with their healthcare provider was mentioned as a significant factor to people's experience of the course. Previous research has highlighted an association between a person's satisfaction with the quality of this relationship [30], their attachment style and/or perceptions of the quality of communication from a healthcare provider [31] and treatment adherence. Consequently the way information is presented and the interpersonal style of the healthcare professional may influence the uptake of health promoting behaviours. In this study, participants commented on feeling supported in a non-judgemental way and at the same time noticed they were being encouraged to take more responsibility for addressing their IAH. This can be a difficult balance for a Diabetes Educator to achieve. The DAFNE-HART programme facilitated this by using motivational interviewing to minimise resistance and maximise collaboration. Participants also appeared to value the mixture of group and one-to-one support over the six-week time period. It may be that being a group of people with similar experiences of struggling with IAH and having the time and space to reflect and test out potential strategies allowed people to make changes, when they had previously failed to do so.

Challenging aspects of the course for some participants included how confident and comfortable they felt in a group setting. In addition, some people found the timing of the BSM scan (to look for new cues) confusing and there were comments regarding the administrative challenges around timing and paperwork. These findings are helpful in order to inform revision of the next version of the DAFNE-HART curriculum and how recruitment, group participation and presentation of the information can be clarified to maximise engagement and understanding.

One of the strengths of this study was the independence of the researchers involved in conducting the interviews and analysing the data. Neither of these researchers were part of the development or delivery of the programme. It was unfortunate that not all 24 participants' views could be represented in this evaluation. Nevertheless, saturation was achieved in that by the end of the study, no new themes were being promulgated. As this is a pilot study, we cannot be sure that the findings will be generalizable to other settings. The two centres delivering the programme have special interest in hypoglycaemia management. Participants commented favourably on the knowledge base of the educators. Nevertheless, many diabetes centres have experienced diabetes educators who may benefit from additional psychological skills training for more complex clinical groups such as those with IAH. Interviews were conducted immediately on course conclusion and it will be important in future research to determine how long the participants were able to sustain their new behaviours and attitudes.

In summary, this study has explored patients' experiences and views about a new structured psychoeducational programme (DAFNE-HART) designed to address IAH. The findings demonstrate improved self-management strategies and cognitive changes around hypoglycaemia with a good level of acceptability of the course material and delivery. Consequently, DAFNE-HART may offer a support structure which enables the principles of optimal diabetes management to be translated into action. Participant comments highlight the role of a group and individual format, a trusting relationship between care provider and patient, a motivational approach to facilitation and explicit psychoeducation on the thoughts maintaining IAH as valuable components of the programme. Further research is needed to determine which components of DAFNE-HART are most effective in improving IAH and also in sustaining its benefits.

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Appendix I: Programme Overview

Week 1	Group session (all day)	
	How low can you go?	
	What causes IAH and what keeps the problem going (vicious cycles)	
	Attention control and identifying novel/subtle hypo cues (body-senses-mind scan)	
	Start to identify individual risk factors for SH (hypoglycaemia management plan)	
Week 2	Group session (all day)	
	The Balancing Act	
	Diary reviews	
	Revising DAFNE principles re. carbohydrate, insulin and exercise (pyramid model) in the	
	context of minimising hypoglycaemia	
	Further review of individual risk factors for SH (hypoglycaemia management plan)	
Week 3	Group session (all day)	
	Thinking Traps & Social Support	
	Diary reviews	
	Introduced the 'thinking traps' (three cartoon metaphors)	
	Linking thoughts to feelings and behaviour (CBT vicious cycle)	
	Managing hypos in a social context (assertiveness; 'diabetes bill of rights')	
Week 4	Individual Face-to-Face (Up to 45 minutes)	
	Educators review what has gone well and what further changes are needed at an	
	individual appointment (Action plans)	
Week 5	Individual Phone call (Up to 45 minutes)	
	Same as week 4 above	
Week 6	Group session (all day)	
	Keeping on Track	
	Diary reviews	
	Review of the course	
	Information regarding driving and hypoglycaemia	
	Q&A session with doctor	
	Understanding lapses and relapse prevention	

Figure Legend for A qualitative evaluation of DAFNE-HART: A psychoeducational programme to restore hypoglycaemia awareness.

Only one figure appears in the paper:

Appendix I: Programme Overview