



Patient Satisfaction with CIMZIA[®] (Certolizumab Pegol) AutoClicks[®] in the UK

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ABSTRACT

Introduction: The CIMZIA[®] AutoClicks[®] pre-filled pen (CZP PFP) was developed to overcome barriers to self-injection, by improving self-injection confidence, reducing fear associated with needle use, and supporting patients with impaired dexterity. The purpose of this research was to gather feedback on injection experience and the usefulness of training materials.

Methods: Eligible patients with rheumatoid arthritis (RA), axial spondyloarthritis (axSpA) or psoriatic arthritis (PsA) were at least 18 years of age and initiated onto the CZP PFP. Routine self-injection training and support were provided by trained specialist nurses. Patient experience (pain and skin reactions, confidence,

satisfaction, and ease of use) was evaluated at visits 1–3 using an amended version of the self-injection assessment questionnaire (SIAQ) v2.0. Nurse and patient feedback on the training materials, and nurse opinions on patient self-injection after self-injection at visit 1, were also collected.

Results: Of 355 patients invited to participate, 196 provided informed consent and 79 participated in all three visits. Patients generally found the CZP PFP easy to use, and self-confidence and satisfaction were high. From visit 1 to visit 3, there was a numerical trend towards improvement in all three aspects of patient experience, most notably in both confidence and satisfaction. After self-injection at visit 1, confidence around safe patient self-injection was higher among nurses than among patients. Meanwhile, “pain and skin reactions” remained low at all visits. Patients thought the training materials contained sufficient information and were easy to understand and useful.

Conclusion: After training, patients generally found the device easy to use and showed high confidence and satisfaction with self-injection. Some patients may have been competent (based on nurse opinion), but initially lacked self-confidence. Increasing self-injection experience, together with patient training and continued support, may have facilitated high patient confidence and satisfaction, thereby potentially overcoming some of the barriers to self-injection.

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Keywords: Biologic; Certolizumab pegol; Patient experience; Rheumatology; Self-injection

Key Summary Points

Why carry out this study?

Despite the availability of innovative and effective biological agents for rheumatic diseases, patients may not experience the full benefits of treatment because of poor medication adherence

The CIMZIA® AutoClicks® pre-filled pen (CZP PFP) was developed to overcome barriers to self-injection, by improving self-injection confidence, reducing fear associated with needle use, and supporting patients with impaired dexterity

The purpose of this research was to gather feedback on injection experience and the usefulness of training materials

What was learned from the study?

After training, patients generally found the device easy to use and showed high confidence and satisfaction with self-injection

Increasing self-injection experience, together with patient training and continued support, may have facilitated high patient confidence and satisfaction, thereby potentially overcoming some of the barriers to self-injection

diseases, patients may not experience the full benefits of treatment because of poor medication adherence [2]. Factors influencing patient adherence include the route of treatment administration and disease-related factors (such as stiffness, hand deformities, and pain) [2, 3]. Self-injection may improve adherence and injection experience for patients taking bDMARDs by increasing their independence and control over when the medication is administered [3, 4]. However, barriers to self-injection using a pre-filled syringe (PFS) include dexterity problems, pain caused by the swelling of joints in the hands, injection anxiety (which may be linked to needle phobia), and lack of confidence [4–6].

Certolizumab pegol (CZP; CIMZIA®) is an Fc-free, PEGylated anti-TNF approved for treatment of chronic inflammatory diseases including moderate-to-severe, active rheumatoid arthritis (RA); axial spondyloarthritis (axSpA), including patients with severe active ankylosing spondylitis (AS); psoriatic arthritis (PsA), and moderate-to-severe plaque psoriasis [7, 8]. CZP is administered subcutaneously and is available for self-administration as a PFS, pre-filled pen (PFP) or an electronic injection device, ava® [1, 4, 7]. The CIMZIA® AutoClicks® PFP (UCB Pharma S.A., Brussels, Belgium), referred to here as the CZP PFP, was recommended for use in all approved indications (which at the time included RA, axSpA, and PsA) and made available in the United Kingdom (UK) in 2016 [9, 10]. Like the other CZP self-injection devices, the CZP PFP was developed in collaboration with OXO, and designed with patient input [4, 9, 11, 12]. It has a button-free delivery system and a wide, non-slip grip to support patients with impaired dexterity (Fig. 1) [9]. The CZP PFP also has a large viewing window, to allow patients to check their medication visually and monitor the progress of the injection, and audible clicks at start and finish to give patients confidence that the full dose has been administered [9, 10]. The retractable needle is not visible to patients during the entire injection process, which may also help reduce fear associated with needle use [10]. Comparative usability studies conducted in 2013 and 2016 showed that patients with RA ranked the CZP PFP as their preferred device

INTRODUCTION

Biological disease-modifying anti-rheumatic drugs (bDMARDs), including anti-tumor necrosis factor inhibitors (anti-TNFs), are used for the treatment of chronic inflammatory rheumatic diseases [1]. Despite the availability of innovative and effective biological agents for these

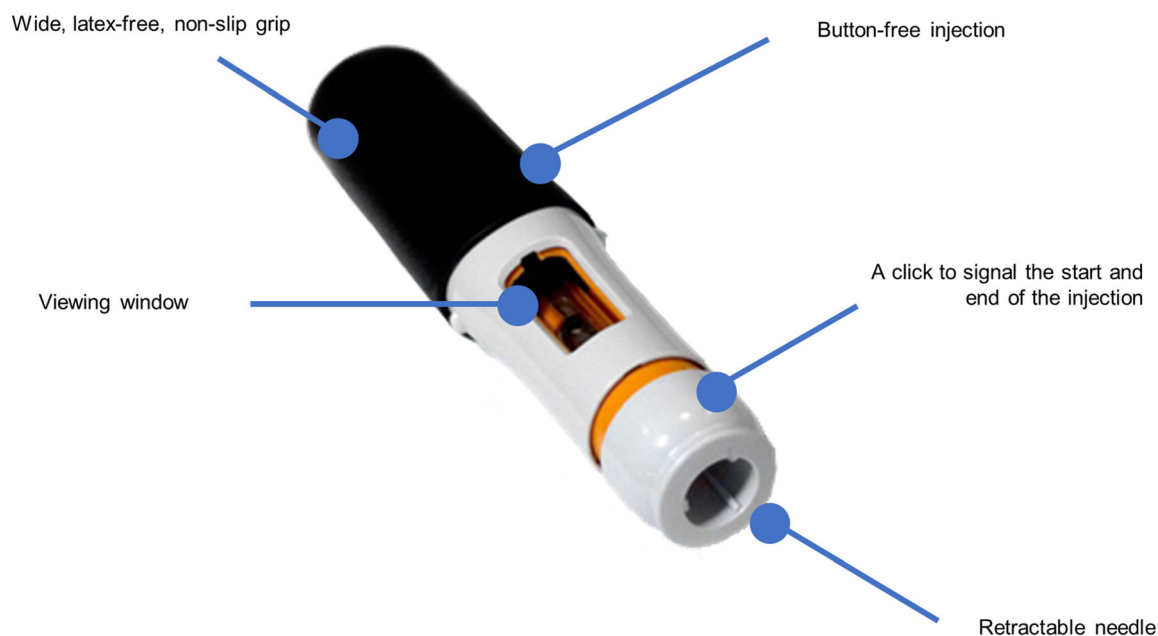


Fig. 1 Key features of the CZP PFP. *CZP* certolizumab pegol, *PFP* pre-filled pen

compared to adalimumab, etanercept, and golimumab PFPs [12].

The first commercial launch of the CZP PFP took place in the UK. During routine appointments, patients using the device were provided with self-injection training and support by trained specialist nurses from Healthcare at Home Ltd. (hereafter referred to as the service provider). The purpose of this research was to use the UK launch of the CZP PFP to evaluate the views, feelings, and experiences of patients using the device, as well as service provider nurses, and to gather their feedback with respect to the available support and training materials.

METHODS

Participants

Patient Recruitment for Market Research

Market research was conducted to assess patient experience (PEx) with the CZP PFP (UCB Pharma S.A., Brussels, Belgium), and the effectiveness of the training materials. Eligible patients were at least 18 years of age, had a confirmed diagnosis of RA, axSpA, or PsA, and

were initiated onto the CZP PFP with a dosing regimen of once every 2 weeks (Q2W). Patients may have been anti-TNF-naïve, have switched from another anti-TNF therapy (including one administered by an autoinjector), or have been transitioning from the PFS to the PFP formulation of CZP, as prescribed by their physician. Patients were excluded if they were not able to complete the questionnaire, either because of visual impairment or because they were unable to read or understand the questionnaire in English. Since this was a market research study, and therefore falls outside the remit of the Research Governance Framework (RGF), prior approval of the protocol by an ethics committee was not required. This approach is compliant with the British Healthcare Business Intelligence Association (BHBI) ethical and legal guidelines for healthcare market research [13]. All patients who participated in the study provided informed consent. All the results presented in this article are in aggregate form, and no personally identifiable information was used in the analyses and presentation of these data.

All patients using the CZP PFP, regardless of treatment center or market research participation, were offered self-injection training and support during routine visits. This was provided

by specialist service provider nurses, who had received appropriate training and followed a standardized clinical protocol. Patients were recruited from UK referring centers that were supported by service provider nurses, and did not have a prior objection to participation. Prospective patients were invited to consider participation in the research during a pre-scheduling call (Fig. 2). Prior to their first routine visit (week 0), a letter was sent to patients who were willing to participate, detailing the purpose of the study and intended use of the data collected. The study was discussed with the patient, who then provided informed, electronic consent and could opt out of the study at any point. Electronic consent was then requested repeatedly throughout the study, i.e., each time before data were collected.

Study Design

Survey Instrument

PEX pre- and post-use of the CZP PFP was evaluated via an amended version of the self-injection assessment questionnaire (SIAQ) version

2.0 [5]. The SIAQ version 2.0 is a validated survey instrument used to assess patient-reported self-injection experience at baseline (i.e., before injection; pre-SIAQ) and after injection with a new device, e.g., an autoinjector (post-SIAQ). To reduce the patient burden of participating in the market research, the amended pre- and post-SIAQ included only the domains most relevant to assessment of PEx with the device. For the pre-SIAQ these were “self-confidence” and “satisfaction with self-injection”, and for the post-SIAQ, “self-confidence”, “pain and skin reactions”, “ease of use”, and selected questions from “satisfaction with self-injection”. It was anticipated that patients who were more afraid of injections would be more likely to opt out of the study, leading to a ceiling effect in the “feelings about injections” domain. The domains omitted were therefore “feelings about injections” (from the pre- and post-SIAQ) and “self-image” (post-SIAQ only), together with selected questions from the “satisfaction with self-injection” domain (post-SIAQ only).

Patients completed a pre-SIAQ before the first injection (Table S1 in the supplementary material) and a post-SIAQ within 0.5–1 h after

	Pre-scheduling call	Visit 1 (Week 0)	Visit 2 (Week 2)	Visit 3 (Week 4)
Patient				
Invitation to participate	✓			
Evaluation of training materials ^a		✓		
Pre-SIAQ		✓		
Post-SIAQ		✓	✓	✓
Nurse				
Evaluation of training materials ^b		✓		
Evaluation of patient self-injection		✓		

Fig. 2 Patient satisfaction study design. ^aPatients were provided with training materials prior to self-injection. ^bService provider nurses provided feedback on the training

materials once they had trained five patients at their first visit. *SIAQ* self-injection assessment questionnaire

every self-injection (Table S2). Self-injections were conducted on three consecutive visits, at weeks 0, 2, and 4. In the post-SIAQ, patient responses to each item about self-confidence, satisfaction with self-injection, and pain and skin reactions were rated on a 5-point semantic Likert-type scale; responses to items relating to ease of use were rated on a 6-point semantic Likert-type scale. A score of 1 corresponded to a negative experience and 5/6 a positive experience (except for the pain and skin reactions domain, for which this scale was reversed). In order to compare scores across different domains, patient responses for each item were transformed into a score ranging from 0 (worst experience, or lowest pain and skin reactions) to 10 (best experience, or highest pain and skin reactions); the transformed scores for items within each domain were then averaged to give a domain score.

To provide a proxy measure of patient competence, nurses evaluated the safety and effectiveness of the patients' self-injection technique after their first self-injection at visit 1. Nurses were asked two questions after each patient had self-injected: (a) "Did the patient self-inject the complete dose of CIMZIA® (certolizumab pegol) with the pre-filled pen?"; and (b) "Can the patient safely self-inject with the pre-filled pen?".

Training Material Evaluation

The training materials consisted of a training video, a step-by-step guide, and a frequently asked questions (FAQs) booklet (all provided to patients prior to their first visit at week 0), as well as a reusable demonstration device (RDD; provided to nurses only). At visit 1, patients were asked whether they had reviewed the training materials. Those who had not were asked why, and offered the opportunity to review the training video and step-by-step guide during the visit. Prior to receiving nurse training and self-injecting, patients who had accessed the training materials either before or at visit 1 were asked to provide feedback on the training video and step-by-step guide by completing a questionnaire (Table S3). After delivering training at five unique first patient visits, service provider nurses were asked to provide feedback via a questionnaire on the value of the

training video, step-by-step guide, FAQs booklet, and RDD (Table S4).

Patient Cohorts and Analyses

The *opt-in cohort* comprised all patients who participated in visit 1. The *visit 1 cohort* consisted of patients who completed the first visit at week 0, even if they did not complete visit 2 or visit 3. The *longitudinal cohort* consisted of patients who had completed the surveys during all three visits, at weeks 0, 2, and 4. Subgroups were analyzed on the basis of gender and disease indication. Demographic data were collected for the opt-in cohort.

RESULTS

Patient Disposition and Demographics

A total of 355 patients from eligible UK centers were invited to take part in the study, 196 of whom provided informed consent and participated in visit 1 (the opt-in cohort) (Fig. 3). A total of 195 patients completed visit 1 (visit 1 cohort); one patient from the opt-in cohort did not record a response for the pre-SIAQ at visit 1 and was therefore excluded from this cohort. Of the 195 patients completing visit 1, 121 also completed visit 2, and 79 completed visit 3. Therefore, a total of 79 patients formed the longitudinal cohort (Fig. 3).

Patient demographic data were collected for the opt-in cohort ($n = 196$) during visit 1. The mean age was 51.2 years (standard deviation [SD] 14.4) and the majority were female ($n = 125/196$; 63.8%). Over half of the patients ($n = 104/196$; 53%) were diagnosed with RA, 43/196 (22%) with axSpA, and 41/196 (21%) with PsA. The majority of patients perceived their disease to be moderate ($n = 87/196$; 44.4%) or severe ($n = 95/196$; 48.5%); only 14/196 (7.1%) perceived their disease to be mild. At visit 1, 161/196 (82.1%) patients were taking the loading dose of CZP and 35/196 (17.9%) the maintenance dose. Among the opt-in cohort, 109/196 (56%) had prior experience of self-injecting for a medical condition, and

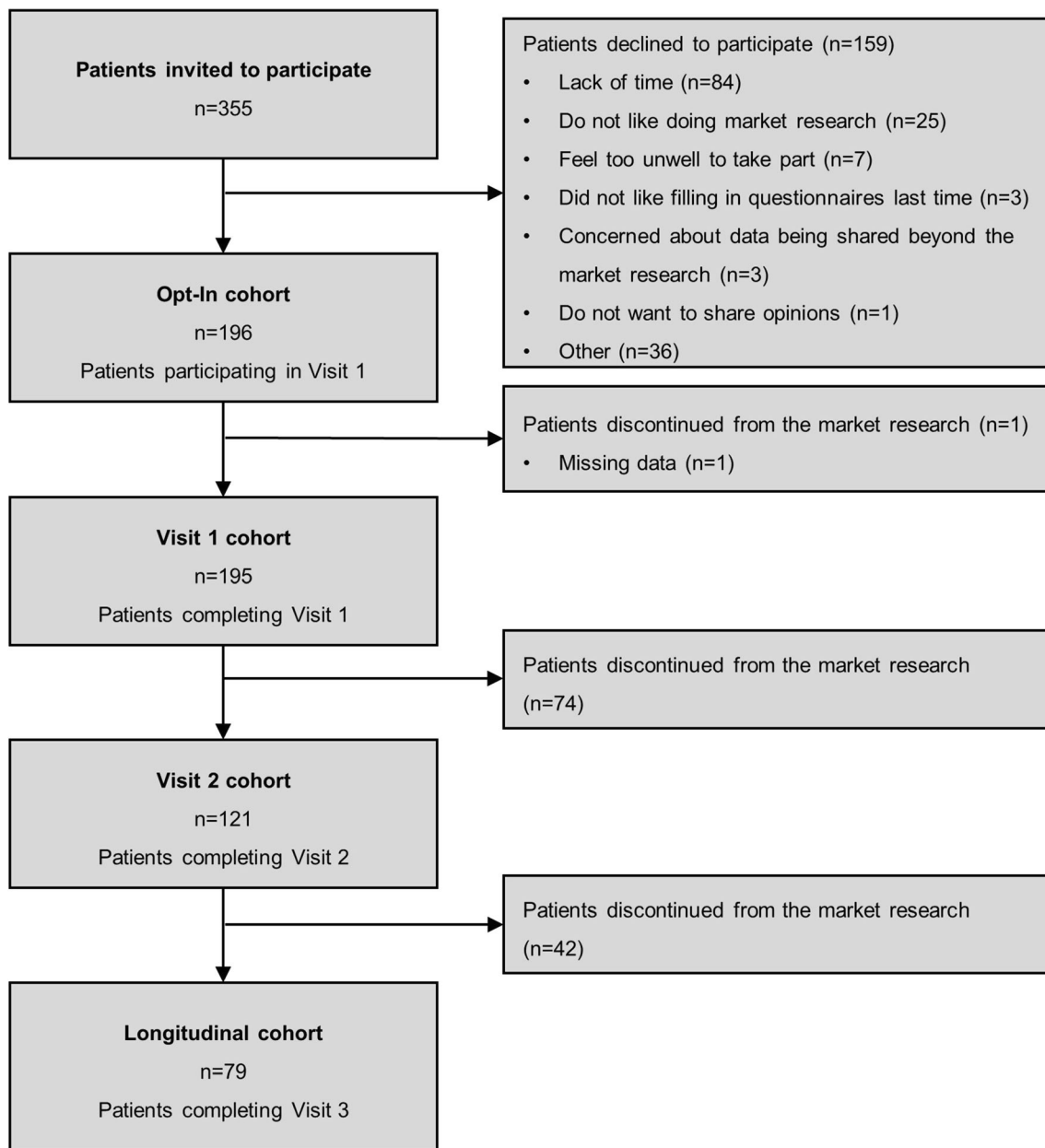


Fig. 3 Patient disposition

96/196 (49%) had previously been treated with biologics (Table 1).

Evaluation of Patient Self-Injection

In the longitudinal cohort, the visit 1 pre-SIAQ (baseline) and visits 1–3 post-SIAQ scores for “self-confidence”, “ease of use”, and “satisfaction with self-injection” were high (Fig. 4).

There was a numerical tendency towards improvement in the scores for these domains from the visit 1 pre-SIAQ (baseline) to the visit 1 post-SIAQ, and through visits 2 and 3. This improvement was most prominent for “self-confidence” and “satisfaction with self-injection”. Meanwhile, post-SIAQ scores for “pain and skin reactions” remained low at all three visits (Fig. 4).

Table 1 Patient demographics and disease characteristics (opt-in cohort; $n = 196$)

	Opt-in cohort ($n = 196$)
Age, mean (SD) (years)	51.2 (14.4)
Age, n (%) (years)	
18–29	9 (4.6)
30–39	33 (16.8)
40–49	37 (18.9)
50–59	45 (23.0)
60–69	46 (23.5)
70–79	23 (11.7)
≥ 80	3 (1.5)
Gender, n (%)	
Female	125 (63.8)
Male	70 (35.7)
Not recorded	1 (0.5)
Indication, n (%)	
Rheumatoid arthritis ^a	104 (53)
Axial spondyloarthritis ^b	43 (22)
Psoriatic arthritis ^c	41 (21)
Other ^d	5 (3)
Not provided	3 (1)
Patient-perceived disease severity ^e , n (%)	
Mild	14 (7.1)
Moderate	87 (44.4)
Severe	95 (48.5)
Dosage, n (%)	
Loading dose (two injections, Q2W)	161 (82.1)
Maintenance dose (one injection, Q2W)	35 (17.9)
Self-injection experience, n (%)	
Yes	109 (55.6)
No	87 (44.4)

Table 1 continued

	Opt-in cohort ($n = 196$)
Biologic-naïve, n (%)	
Yes	100 (51.0)
No	96 (49.0)

AS ankylosing spondylitis, *axSpA* axial spondyloarthritis, *PsA* psoriatic arthritis, *RA* rheumatoid arthritis, *Q2W* every 2 weeks, *SD* standard deviation

^a Rheumatoid arthritis includes physician diagnosis of RA, moderate RA, and severe RA

^b Axial spondyloarthritis includes physician diagnosis of axial spondyloarthritis, ankylosing spondylitis, and non-radiographic axSpA

^c Psoriatic arthritis includes physician diagnosis of PsA only

^d Other includes physician diagnosis of all other diagnoses reported

^e Patient's perception of the severity of their disease (not based on any clinical or laboratory criteria)

After self-injection at visit 1, confidence regarding safe self-injection was higher among nurses than among the patients themselves. In the visit 1 cohort, 162/194 (83.5%) patients were very or extremely confident about being able to safely self-inject (Fig. 5a), while 187/196 (95.4%) nurse responses for the opt-in cohort indicated that patients could safely self-inject (Fig. 5b). Nurses also reported that almost all opt-in patients ($n = 186/195$; 95.4%) were able to competently administer a complete CZP dose after the first self-injection at visit 1 (Fig. 5b).

Subgroup analyses of the longitudinal cohort by gender and disease indication revealed that the results for each domain were numerically comparable, as were the general trends over time. Trends were also comparable between patients with and without prior biologic or self-injection experience (Table S5).

Evaluation of Training Materials

Among patients in the opt-in cohort who accessed the training materials, 82/100 (82.0%) and 149/167 (89.2%) thought the quantity of information in the training video and step-by-

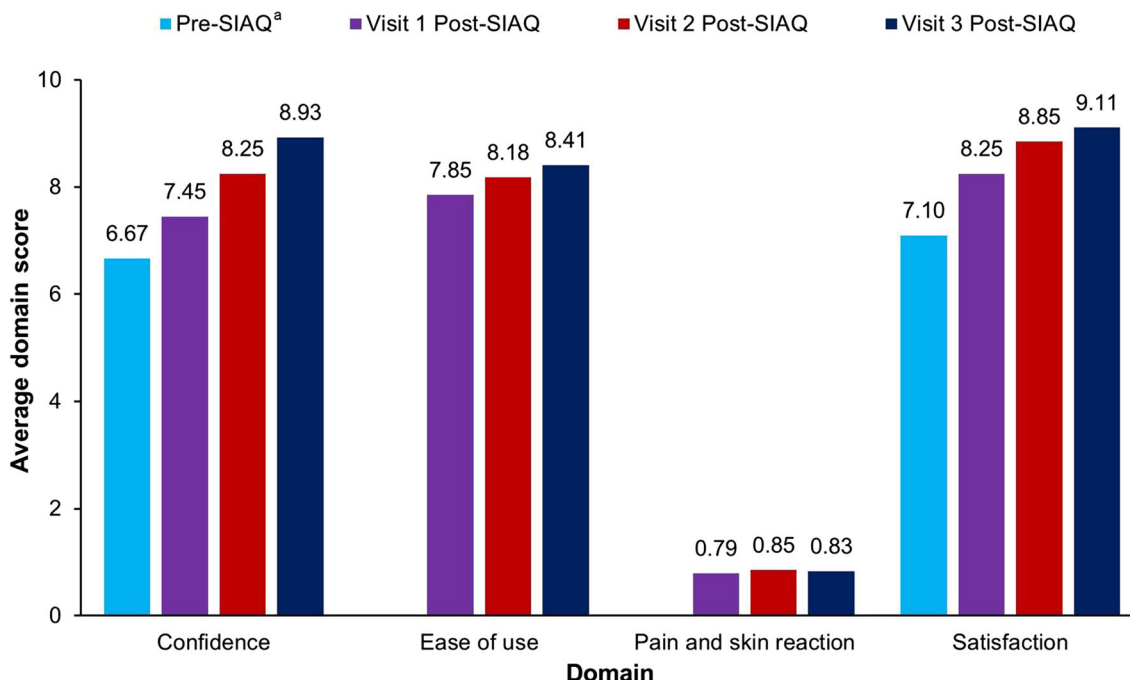


Fig. 4 Average SIAQ domain scores (longitudinal cohort; *n* = 79). ^aPre-SIAQ domain scores represent baseline data, based on patients’ previous way of taking their medication

step guide, respectively, were sufficient to teach the patient how to self-inject (Fig. 6a). Furthermore, 95/100 (95.0%) and 165/170 (97.1%) patients felt that the information provided in each material was easy to understand (Fig. 6b). Each resource was also rated as useful by more than 80% of patients (response at least 7 on a scale of 1 [completely useless] to 10 [completely useful]). Among nurses, the majority (at least 7/9; 77.8%) reported that the available training materials were clear (Fig. 7a) and useful (Fig. 7b). The majority of nurses (8/9; 88.9%) also found it easy or very easy to train patients using the reusable demonstration device. However, one nurse stated: “I found that the majority of the patients I have trained find the training materials very useful, but they still like the reassurance of a nurse being present for support for the first few injections.”

DISCUSSION

Comparative usability studies conducted in 2013 and 2016 showed that patients with RA ranked the CZP PFP as their preferred device

compared with adalimumab, etanercept, and golimumab PFPs [12]. The purpose of this PEx study was to further understand the views, feelings, and experiences of patients using the CZP PFP and service provider nurses, including their feedback with respect to the available training materials.

The results of this study revealed that, after routine training, patients generally found the CZP PFP easy to use, and patient confidence and satisfaction relating to self-injection were high. As expected, increasing self-injection experience, together with routine training and continued support from the service provider nurses, was associated with a numerical trend towards improvement in all three aspects of PEx [5, 14], most notably in both confidence and satisfaction. Nevertheless, after self-injection at visit 1, levels of confidence around safe patient self-injection were higher among nurses than among the patients themselves; this suggests that some patients may initially be competent (based on nurse opinion) but lack confidence. These findings support the importance of suitable training materials and patient support programs to provide reassurance, increase

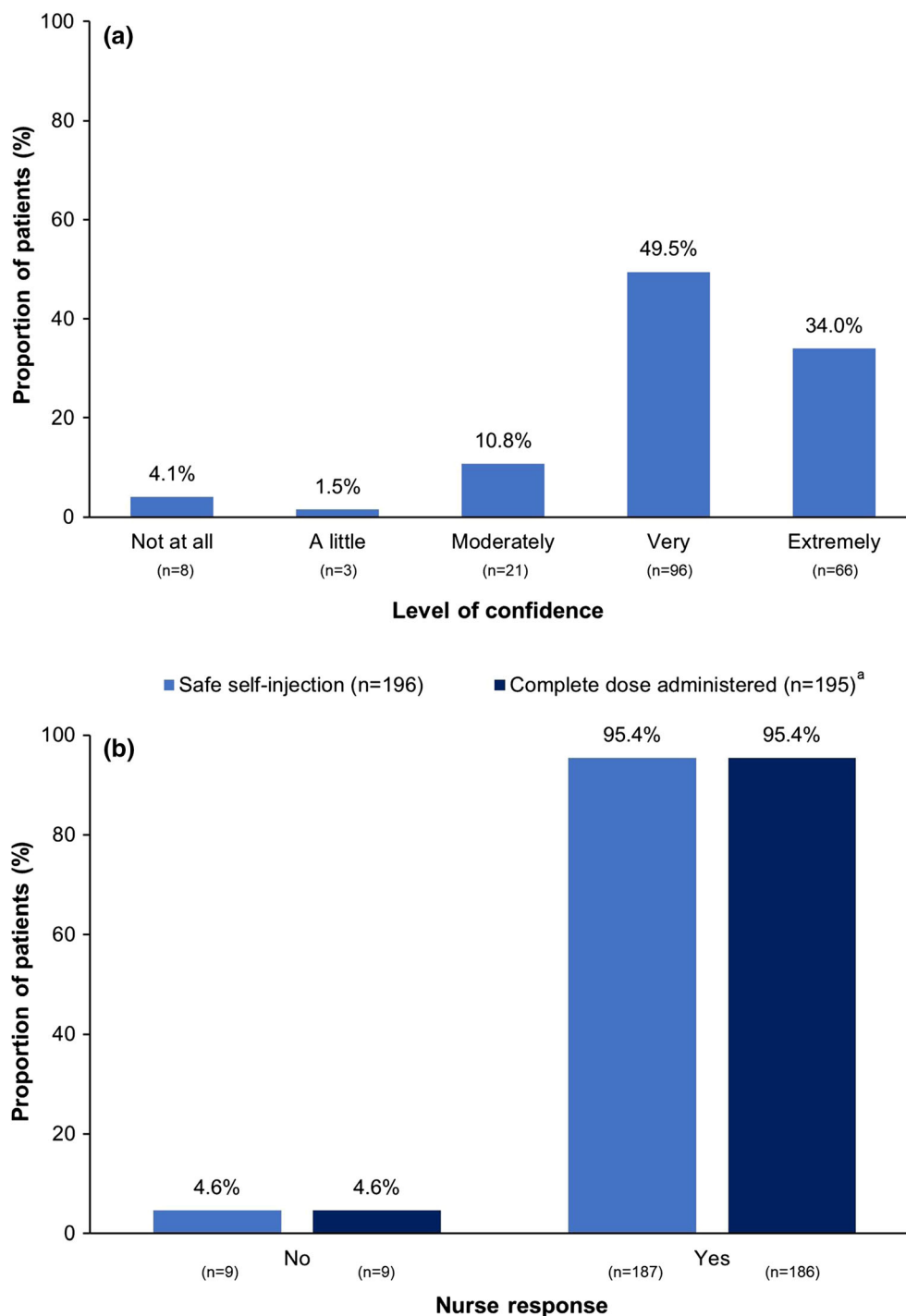


Fig. 5 Evaluation of patient self-injection. **a** Patient-reported confidence around safe self-injection after self-injection at visit 1 (visit 1 cohort; $n = 194$; response

confidence, and facilitate continued self-injection. In the current study, patients reported that the available training materials were effective

missing for 1 patient). **b** Nurse-reported ability of the patient to safely self-inject after self-injection at visit 1 (opt-in cohort; $n = 196$); 1 nurse response missing

and useful, while nurses found the training materials appropriate and clear. However, feedback from a nurse in the current study suggested

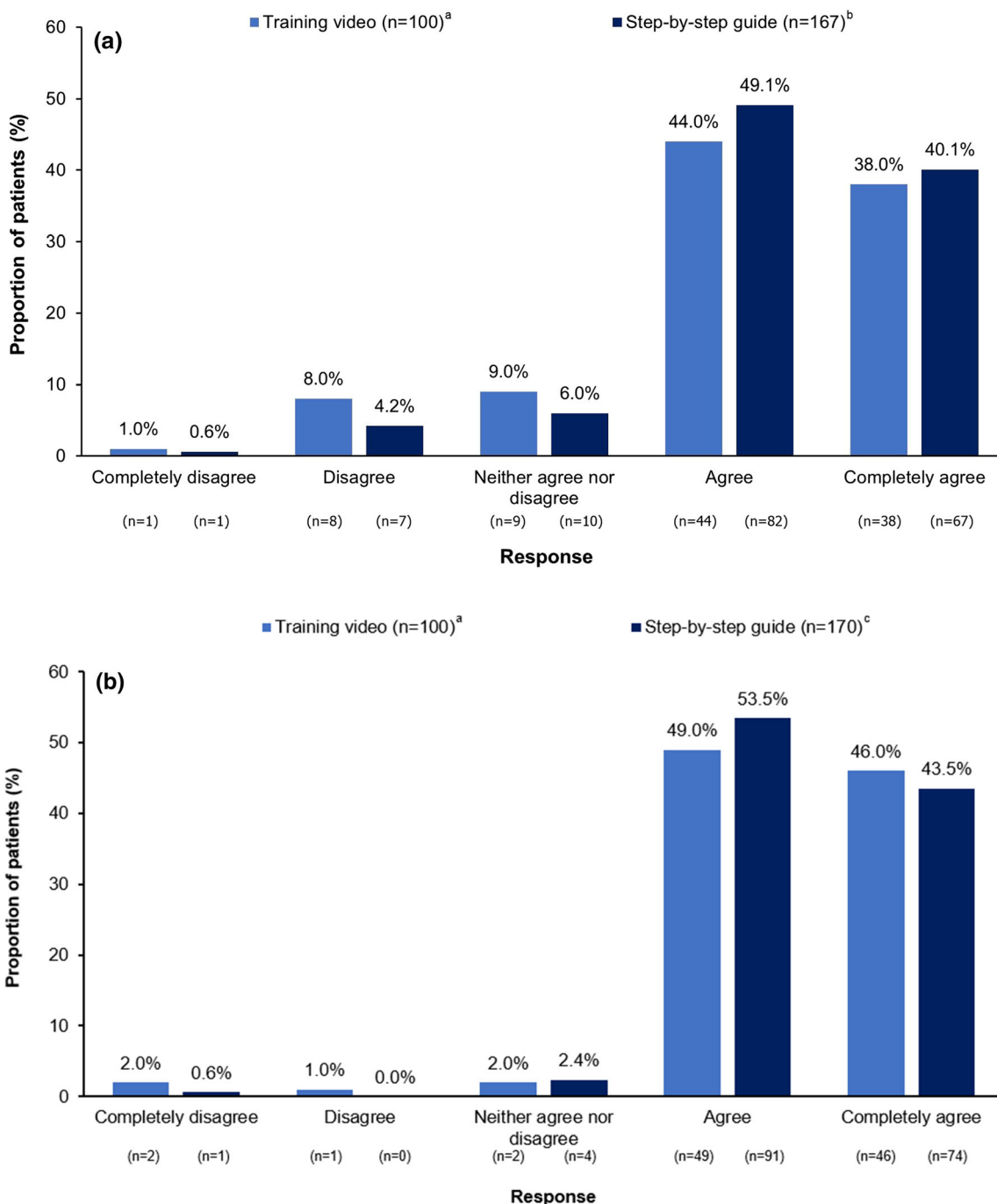


Fig. 6 Patient evaluation of the training materials (opt-in cohort; *n* = 196). **a** “There was enough information in the training video/step-by-step guide to teach me how to self-inject”. **b** “The information in the training video/step-by- that there remains value in the provision of nurse support in addition to multimedia training materials.

step guide was easy to understand”. ^aResponse missing for 96 patients. ^bResponse missing for 29 patients. ^cResponse missing for 26 patients

The route of treatment administration has been reported to influence adherence, with self-injection offering patients convenience and a

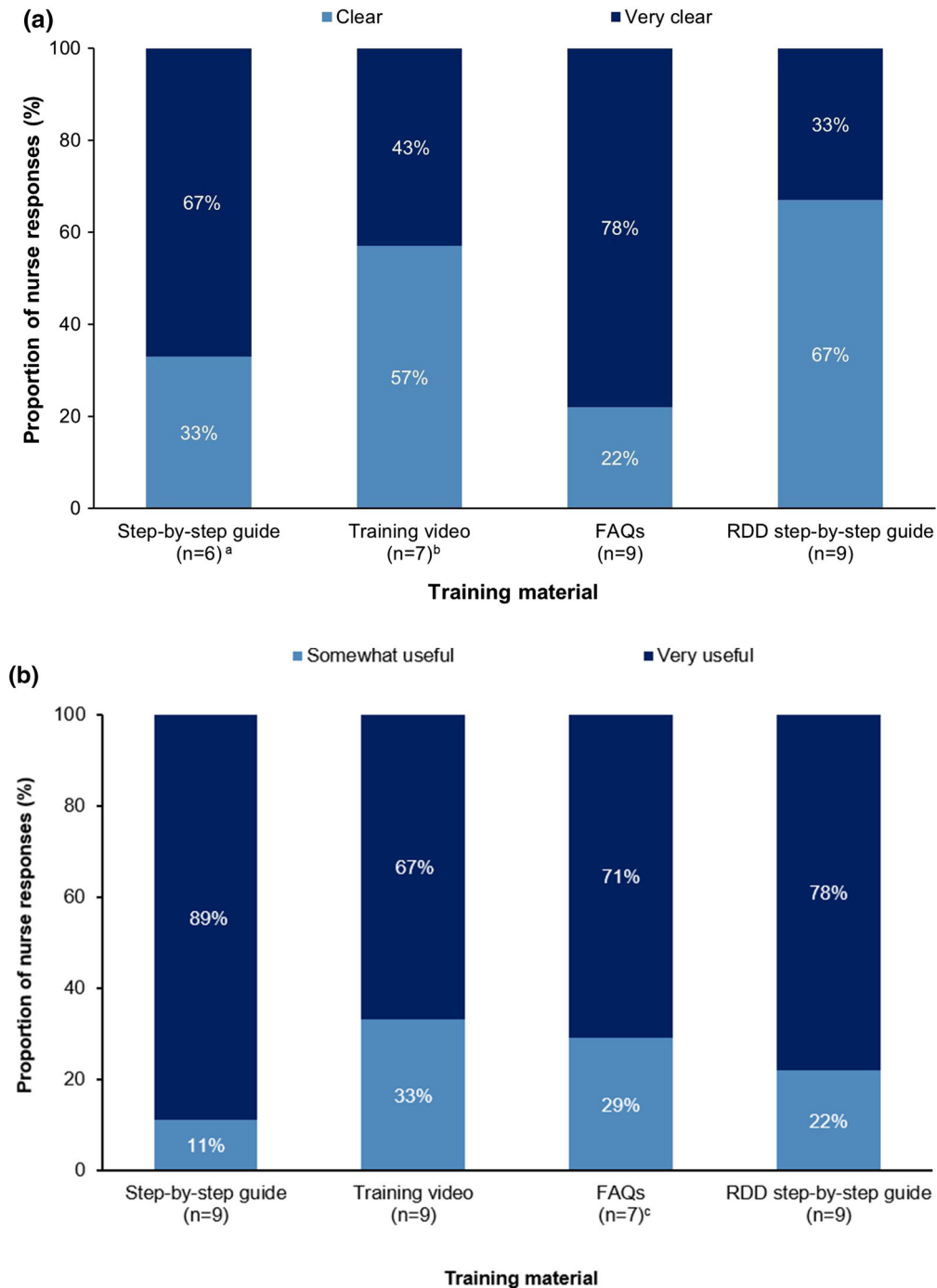


Fig. 7 Nurse evaluation of the training materials ($n = 9$). **a** “How clear was the step-by-step guide/training video/frequently asked questions document in the CIMZIA Patient Guide/reusable demonstration device step-by-step guide (found inside the CIMZIA AutoClicks Demonstration Kit)?” **b** “How useful was the step-by-step guide/training video/frequently asked questions document in the CIMZIA Patient Guide/reusable demonstration device

step-by-step guide (found inside the CIMZIA AutoClicks Demonstration Kit)?”^aThree nurse responses missing.^bTwo nurses responses missing. The response options “Neutral”, “Unclear”, and “Very unclear” were also possible but received no responses. ^cTwo nurse responses missing. The response options “Neutral”, “Not very useful”, and “Not at all useful” were also possible but received no responses. *RDD* reusable demonstration device, *FAQ* frequently asked question

sense of control over their treatment [3]. By increasing patient satisfaction and confidence, as in the current study, suitable training and support could foster a sense of control and enable patients to fully realize the benefits of self-injection. As a result, patient training and support could improve treatment adherence.

The CZP PFP, along with the PFS and reusable electronic injection device, allows patients to choose their preferred device. Provision of a choice of treatment devices could allow patients to align their treatment with their specific preferences and needs [14], which may improve confidence around self-injection. Previous studies have shown that innovative design of self-injection devices such as the CZP PFP can also improve patient confidence and satisfaction with self-injection [12], while the device used can influence the level of pain, ease of use, and convenience reported by patients [15]. The current study builds on this research, and the findings taken together support a holistic approach to enhancing patient confidence, and therefore satisfaction, with self-injection.

The market research was limited by some elements of the SIAQ design. To reduce the patient burden of participating in the market research, the amended pre- and post-SIAQ included only the domains most relevant to assessment of PEx with the device. However, omission of the “feelings about injections” domain (from the pre- and post-SIAQ) and the “self-image” domain (from the post-SIAQ) means that some elements of self-injection experience were not assessed. Furthermore, the inclusion of only one question from the “satisfaction with self-injection” domain in the post-SIAQ may have compromised the validity of scores for this domain. It should also be noted that this study did not include a comparator, and therefore we cannot comment on the relative strength of the CZP PFP compared with other self-injection devices. However, demonstrating superiority of the PFP over, e.g., the PFS would not necessarily be a desirable goal, since providing patients with access to an expansive portfolio of devices offers freedom of choice to those with differing needs [16]. Thus, patient experience should remain central to all studies of self-injection devices, and indeed, this is the

basis on which the SIAQ was originally developed [4, 5].

A further limitation lies in the fact that patients who were most afraid of self-injection may have opted out of the study, reducing the generalizability of these results to the wider patient population. Finally, the longitudinal cohort (patients completing all three visits) included only 79 patients and may not be representative of the entire population of patients using CZP PFP.

CONCLUSIONS

Patients generally found the CZP PFP easy to use, and initially high levels of patient confidence and satisfaction appeared to grow with increasing self-injection experience and continued routine support from service provider nurses. However, some patients may have been competent at self-injection but initially lacked confidence. By establishing a link between provision of training and support, and patient confidence and satisfaction, the current study adds to previous research [12, 15] in support of a holistic approach to overcoming barriers to self-injection. Thus, interventions such as innovative device design, patient self-injection device choice, and training and support, together, may facilitate high levels of patient confidence and satisfaction with self-injection, and therefore treatment adherence.

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Disclosures. Irina Mountian, Richard Bruggaber, Kerri Sunderland, Nicola Tilt, and Boglarka Szegvari are employees of UCB Pharma. Kathryn Bailey was previously affiliated with Healthcare at Home Ltd., Burton upon Trent, UK, but is now affiliated with One Revelation Ltd., Worthing, UK.

Compliance with Ethics Guidelines. Since this was a market research study, and therefore falls outside the remit of the Research Governance Framework (RGF), prior approval of the protocol by an ethics committee was not required. This approach is compliant with the British Healthcare Business Intelligence Association (BHBI) ethical and legal guidelines for healthcare market research [13]. All patients who participated in the present study provided informed consent. All the results presented in this article are in aggregate form, and no

personally identifiable information was used in the analyses and presentation of these data.

Data Availability. The datasets analyzed during the current study are available from Irina Mountian (UCB Pharma) on reasonable request.

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