Patient Perception, Preference and Participation

Patient experiences with intensive combination-treatment strategies with glucocorticoids for early rheumatoid arthritis

Sabrina Meyfroidt, Kristien Van der Elst, Diederik De Cock, Johan Joly, René Westhovens, Marlies Hulscher, Patrick Verschueren

Skeletal Biology and Engineering Research Center, Department of Development and Regeneration, KU Leuven, Leuven, Belgium
Center for Health Services and Nursing Research, Department of Public Health and Primary Care, KU Leuven, Leuven, Belgium
Rheumatology, University Hospitals Leuven, Leuven, Belgium
Scientific Institute for Quality of Healthcare, Radboud University Medical Center, Nijmegen, The Netherlands

A R T I C L E   I N F O

Article history:
Received 28 May 2014
Received in revised form 15 October 2014
Accepted 10 November 2014

Keywords:
Qualitative research
Early rheumatoid arthritis
Intensive combination-treatment strategies
Patient perspective

A B S T R A C T

Objectives: To investigate patients’ experiences with intensive combination-treatment strategies with glucocorticoids (ICTS-GCs) in the early phase of early rheumatoid arthritis (ERA) treatment.

Methods: We interviewed 26 participants individually, 4–6 months after initiation of ICTS-GCs (t1). Fourteen participants from the same sample took part in one of three focus groups at least 1 year after treatment initiation (t2). Each interview was audio-recorded, literally transcribed and thematically coded.

Results: The participants described concerns and feelings about ICTS-GCs that changed over time; for example, a fear of side effects diminished when the treatment effects were beneficial or expected side effects did not materialize. Moreover, participants indicated additional information needs at t1 and t2. The most used sources of information were healthcare professionals, relatives, and the Internet. Furthermore, participants reported on their relationship with healthcare professionals and the need for trust and reassurance, especially at t1. Lastly, participants described their personal self-management strategies.

Conclusion: Despite their concerns at treatment initiation, most participants had positive experiences with ICTS-GCs.

Practice implications: Healthcare professionals should be aware that, in the early phase of treatment, they can address patients’ concerns, they are the most important information source, they need to create a relationship of trust, and guide patients in self-management strategies.

© 2014 Elsevier Ireland Ltd. All rights reserved.

1. Introduction

Early rheumatoid arthritis (ERA) is a chronic, systemic, inflammatory disease characterized by articular cartilage and bone destruction [1]. To successfully treat ERA, clinical remission must be achieved as soon as possible. Treatment guidelines recommend one or multiple synthetic disease-modifying anti-rheumatic drugs (DMARDs) as initial treatment [1–3]. In ERA, glucocorticoids (GCs) given in addition to synthetic DMARDs as monotherapy or in combination, substantially reduce the progression of joint damage, especially when treating ERA to target. Moreover, intensive combination-treatment strategies with glucocorticoids (ICTS-GCs), combining DMARDs with GCs, have been shown to be comparable with intensive treatment strategies with biologic agents, but the cost is significantly less [4–8]. Hence, prescription of ICTS-GCs could lead to a better outcome in ERA at population level without unnecessarily increasing costs for society.

A heterogeneous set of barriers, which we identified in a previous qualitative study, has highlighted the complexity of prescribing ICTS-GCs for ERA in daily clinical practice from the perspective of healthcare professionals [9]. Some rheumatologists questioned the value of a combination strategy, others the effectiveness or the dosage of individual compounds. Additional barriers for prescribing ICTS-GCs included “the need for patient education”, “concerns about applicability to the individual patient”, “difficulties with breaking routine”, “interference with organizational structures and processes”, “time constraints” and “lack of financial compensation”.

To get a complete picture of the potential advantages and disadvantages of ICTS-GCs for ERA and to facilitate using ICTS-GCs in daily clinical practice, it is important to consider both the

Please cite this article in press as: Meyfroidt S, et al. Patient experiences with intensive combination-treatment strategies with glucocorticoids for early rheumatoid arthritis. Patient Educ Couns (2014), http://dx.doi.org/10.1016/j.pec.2014.11.011
healthcare professional perspective and patient experiences. Understanding patient experiences on ICTS-GCs is crucial, and it is a key component of patient-centered care in health education and treatment decision-making. Hence, a better understanding of patient experiences could increase the awareness of healthcare professionals so that they become more responsive to patient preferences when they prescribe ICTS-GCs. This could result in better treatment adherence, improved health status, and better satisfaction with care [10–14].

To the best of our knowledge, patient experiences of combination therapy have only been explored in populations with long-term disease [15,16]. How patients with ERA experience ICTS-GCs in the early phase of treatment is still unknown. However, perceptions of ICTS-GCs might change with longer disease duration, patient education, and better understanding of the disease based on their own experiences or those of other patients [17,18]. This might be especially true in the course of a remission induction step down approach, when patients with ERA are confronted with the need to take many new medicaments, because unfortunately this occurs when they have just been diagnosed with a chronic disease that they do not yet fully understand [19]. Hence, the purpose of this study is to gain a longitudinal, in-depth understanding of patient experiences with ICTS-GCs at two times in the early phase of their treatment.

2. Methods

2.1. Design

This longitudinal, qualitative, phenomenological study involved interviews at two times in the 1st year of ICTS-GCs for ERA. A phenomenological study describes personal “lived experiences” to better understand their structure and meaning [20]. We set up individual interviews within 4–6 months after treatment initiation (t1). Individual interviews enabled the participants to display their personal experiences with ICTS-GCs, which could be a delicate topic because they had been recently diagnosed. This timeframe was chosen to ensure that the participants had gained enough experience with the intensive treatment in a remission induction step down approach, and to keep the time after treatment initiation short. Next, we conducted focus groups at least 1 year after treatment initiation (t2). We assumed that the participants would be more familiar with the treatment by that time and that they could compare and discuss their experiences with peers, facilitating the generation of additional information. We considered a period of more than 1 year after treatment initiation to be enough to have completed the medication tapering in the step-down schedule.

2.2. Recruitment of participants

We drew a purposive sample of patients with ERA participating in the Care for Early Rheumatoid Arthritis (CareRA) trial [21]. This trial is an on-going, 2 years, prospective, multicenter, randomized, controlled trial (EudraCT number: 2008–007225–39), rooted in daily practice across 18 rheumatology practices in Flanders. The objective of CareRA is to determine the optimal combination of synthetic DMARDs (methotrexate [MTX], MTX + sulfasalazine, or MTX + leflunomide) and the ideal dose of associated GCs for remission induction regimens. The participants received educational material in different formats about the disease and ICTS-GCs (leaflets, DVDs, and medication schemes) at treatment initiation. The patients enrolled in the CareRA trial met the inclusion criteria of (1) being 18 years old or more, (2) having a diagnosis of RA as defined by the 1987–American College of Rheumatology classification criteria, and (3) having ERA defined as a disease duration of 1 year or less at diagnosis.

All patients who had been considered for ICTS-GCs in the CareRA trial were eligible for the individual interview if an interview date could be fixed within 4–6 months after treatment initiation. Forty-six patients listed in the CareRA database were eligible. We selected patients from the list of eligible patients to reflect diversity in terms of different types of practices and geographic regions. Moreover, patients who continued their treatment, as well as those who decided to, or had to, discontinue treatment were invited. We asked patients’ rheumatologist to invite their patient(s) and 17 out of the 20 rheumatologists agreed to participate in the recruitment process. Ultimately 11 rheumatologists gave us the contact details for 26 patients, who all agreed to participate. After interviewing these 26 participants, we concluded that data saturation had been reached because no new experiences were identified in the last three consecutive interviews.

At the end of his/her individual interview, each of the 26 participants was invited to join a focus group, and 18 agreed. One patient was excluded because the patient decided to discontinue treatment including follow-up care. The remaining seven declined to participate in focus group interviews because they did not want to share their experiences in a group. Unfortunately, four patients reconsidered their participation because of scheduling conflicts. Ultimately, we conducted three focus groups that included four to six participants each, totalling 14 participants. Fig. 1 shows a flow chart of participant recruitment. Table 1 presents the demographics of the study population. The characteristics of the individual interviewees and focus group participants did not differ.

2.3. Data collection

The Human Research Ethics Committee of the Leuven University Hospitals granted ethics approval. All participants gave written informed consent.

Semi-structured individual interviews took place between April and August 2012. SM and KE, who were not directly involved in...
facilitate a permissive environment during the interview, the interviewers adopted the character of the “naïve” researcher and guaranteed anonymity. The interviews lasted approximately 45 min, ranging from 20–90 min.

The three focus groups were conducted in March 2013, at least 1 year after the 14 participants started treatment. The focus groups met in an accessible and non-clinical environment, and lasted approximately 1 h each. The principal investigator (SM) moderated all focus groups, and KE or DC observed and took field notes.

The self-constructed interview guides for the individual interviews and the focus groups (Table 2) were based on (1) barriers and facilitators for adherence to long-term medication treatments as identified from literature and (2) our own previous interviews with rheumatologists and nurses participating as investigators in the CareRA trial [9,22]. All individual interviews and focus groups were audio-recorded and transcribed verbatim.

### 2.4. Data analysis

We used the Qualitative Analysis Guide of Leuven (QUAGOL) to analyze the interview data of both the individual interviews and the focus groups [23]. The QUAGOL is a theory and practice-based guide to capture the rich insights of different types of qualitative datasets, even if focus group transcripts are more voluminous and unstructured compared to individual interview transcripts. The guide is built on the case-oriented approach, characterized by a continual balancing between within-case and cross-case analysis, a forward–backward dynamic using the constant comparative method and the interdisciplinary team approach. The data analysis procedure consists of a thorough preparation of the coding process, implying only paper and pencil work, and the actual coding process, using a qualitative software program. We used NVivo9 software (QSR International, Melbourne, Australia). The data collection and analysis were cumulative iterative. Two researchers (SM and KE) independently reviewed and coded the transcripts of the individual interviews, and three researchers (SM, KE, and DC) independently reviewed and coded the transcripts of the focus groups. The researchers discussed the individual coding and resolved disagreements until consensus was reached in multiple peer debriefings during and after data collection. Furthermore, additional credibility checks were performed by one rheumatologist and one independent patient researcher on the frames extracted during the analysis.

### 3. Results

Four main themes emerged as important to our participants with ERA regarding their experiences with ICTS-GCs:

1. The participants described concerns and feelings about ICTS-GCs that changed over time.
2. They indicated information needs about different topics at $t_1$ and $t_2$.

### Table 1
Demographics of the study population.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Individual interviewees at $t_1$ (n = 26)</th>
<th>Focus group participants at $t_2$ (n = 14*)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median (range) age in years</td>
<td>55 (22–68)</td>
<td>57 (23–66)</td>
</tr>
<tr>
<td>Median (range) patients’ general health scores (100 mm VAS)</td>
<td>24 (0–64)</td>
<td>38 (0–80)</td>
</tr>
<tr>
<td>Median (range) patients’ pain scores (100 mm VAS)</td>
<td>22 (0–65)</td>
<td>37 (0–80)</td>
</tr>
<tr>
<td>Median (range) patients’ fatigue scores (100 mm VAS)</td>
<td>29 (0–64)</td>
<td>37 (0–80)</td>
</tr>
<tr>
<td>Gender, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Men</td>
<td>8 (31)</td>
<td>5 (36)</td>
</tr>
<tr>
<td>Women</td>
<td>18 (69)</td>
<td>9 (64)</td>
</tr>
<tr>
<td>Site of recruitment, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Private practice</td>
<td>9 (36)</td>
<td>3 (21)</td>
</tr>
<tr>
<td>General hospital</td>
<td>8 (28)</td>
<td>5 (36)</td>
</tr>
<tr>
<td>Academic hospital</td>
<td>9 (36)</td>
<td>6 (43)</td>
</tr>
<tr>
<td>Geographic location of site, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Antwerp</td>
<td>1 (4)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Limburg</td>
<td>9 (35)</td>
<td>4 (29)</td>
</tr>
<tr>
<td>Flemish Brabant</td>
<td>12 (45)</td>
<td>8 (57)</td>
</tr>
<tr>
<td>East Flanders</td>
<td>1 (4)</td>
<td>1 (7)</td>
</tr>
<tr>
<td>West Flanders</td>
<td>3 (12)</td>
<td>1 (7)</td>
</tr>
<tr>
<td>Healthcare professionals involved in ERA care for participants, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rheumatologist</td>
<td>26 (100)</td>
<td>14 (100)</td>
</tr>
<tr>
<td>Nurse</td>
<td>8 (31)</td>
<td>6 (43)</td>
</tr>
<tr>
<td>General practitioner</td>
<td>14 (54)</td>
<td>8 (57)</td>
</tr>
<tr>
<td>Other</td>
<td>4 (15)</td>
<td>3 (21)</td>
</tr>
<tr>
<td>Use of additional medication to treat comorbidities, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>12 (46)</td>
<td>6 (43)</td>
</tr>
<tr>
<td>No</td>
<td>14 (54)</td>
<td>8 (57)</td>
</tr>
<tr>
<td>Treatment progress, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient decided to discontinue treatment</td>
<td>1 (4)</td>
<td>–</td>
</tr>
<tr>
<td>Treatment failures* in the 1st year</td>
<td>4 (15)</td>
<td>3 (21)</td>
</tr>
<tr>
<td>Treatment failures* after 1 year</td>
<td>1 (4)</td>
<td>1 (7)</td>
</tr>
<tr>
<td>Treatment responders</td>
<td>20 (77)</td>
<td>10 (72)</td>
</tr>
</tbody>
</table>

### Table 2
Initial interview guides.

<table>
<thead>
<tr>
<th>Interview content</th>
<th>Individual interview (t_1, 4–6 months after treatment initiation)</th>
<th>Focus group (t_2, at least 1 year after treatment initiation)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>– Describe your experiences with ICTS-GCs.</td>
<td>– Describe your experiences with ICTS-GCs.</td>
</tr>
<tr>
<td></td>
<td>– What did you do when they first gave you information about the treatment?</td>
<td>– Describe your experiences with the medication tapering.</td>
</tr>
<tr>
<td></td>
<td>– How do you feel about the individual medicaments? What is your experience with these medicaments?</td>
<td>– How do you feel about the individual medicaments? What is your experience with these medicaments?</td>
</tr>
<tr>
<td></td>
<td>– What promoted and hindered you to start treatment and to take treatment advice?</td>
<td>– What promoted and hindered you to take treatment advice?</td>
</tr>
<tr>
<td></td>
<td>– What impact does the treatment have on you (and your life)?</td>
<td>– What impact does the treatment have on you (and your life)?</td>
</tr>
<tr>
<td></td>
<td>– What support did you need/receive?</td>
<td>– What support did you need/receive?</td>
</tr>
</tbody>
</table>

Please cite this article in press as: Meyfroidt S, et al. Patient experiences with intensive combination-treatment strategies with glucocorticoids for early rheumatoid arthritis. Patient Educ Couns (2014), http://dx.doi.org/10.1016/j.pec.2014.11.011
3. They reported on the influence of their relationship with healthcare professionals and the need for trust and reassurance, especially at \( t_1 \).

4. They described their personal self-management activities to support daily routine and how they changed over time.

Table 3 presents the key findings of participant experiences with ICTS-GCs reported at \( t_1 \) and \( t_2 \). Table 4 provides quotes of participants to illustrate the themes.

### Table 3

<table>
<thead>
<tr>
<th>Concerns and feelings about ICTS-GCs</th>
<th>Treatment initiation</th>
<th>4–6 months after treatment initiation</th>
<th>At least 1 year after treatment initiation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Individual drugs</td>
<td>Fear of GCs</td>
<td>Fear of MTX</td>
<td>Fear of MTX</td>
</tr>
<tr>
<td>Number of pills</td>
<td></td>
<td>Current intake too high</td>
<td>Current intake all right</td>
</tr>
<tr>
<td>Concerns</td>
<td>Side effects, long-term consequences, feeling unhealthy, medication dependence</td>
<td>Side effects, long-term consequences, feeling unhealthy, medication dependence</td>
<td>Side effects, long-term consequences, re-experience flares, treatment effectiveness</td>
</tr>
<tr>
<td>Information needs over time</td>
<td>Missing information</td>
<td>Disease evolution, therapeutic aids, medication and its side effects, lifestyle advice</td>
<td>Disease evolution, therapeutic aids, future prospects, cause of ERA</td>
</tr>
<tr>
<td>Information sources</td>
<td>HCP (+information package)</td>
<td>HCP</td>
<td>HCP</td>
</tr>
<tr>
<td></td>
<td>Relatives</td>
<td>Relatively</td>
<td>Relatively</td>
</tr>
<tr>
<td></td>
<td>Internet</td>
<td>Internet</td>
<td>Internet</td>
</tr>
<tr>
<td>Relationship with HCP</td>
<td></td>
<td>Adequate: shared decision-making</td>
<td>Adequate: shared decision-making</td>
</tr>
<tr>
<td>Patients’ involvement</td>
<td>Limited: passively taking advice</td>
<td>Trust</td>
<td>Trust</td>
</tr>
<tr>
<td>Patients’ needs</td>
<td></td>
<td>Adequate: shared decision-making</td>
<td>Trust</td>
</tr>
<tr>
<td></td>
<td>Reassurance</td>
<td>Trust</td>
<td>Trust</td>
</tr>
<tr>
<td>Self-management in daily living</td>
<td>In search of routine</td>
<td>New routine</td>
<td>Fixed routine</td>
</tr>
<tr>
<td>Adaptation</td>
<td></td>
<td>Developing coping and self-care skills</td>
<td>Increasing coping and self-care skills</td>
</tr>
<tr>
<td>Tools</td>
<td>Medication scheme, pillbox, tray, calendar, reminder, backup medication</td>
<td>Medication scheme, pillbox, tray, calendar, reminder, backup medication</td>
<td></td>
</tr>
</tbody>
</table>

ICTS-GCs = intensive combination-treatment strategies with glucocorticoids, GCs = glucocorticoids, MTX = methotrexate, ERA = early rheumatoid arthritis, HCP = healthcare professionals.

### 3.1. Concerns and feelings about ICTS-GCs

At \( t_1 \), many participants mentioned being afraid of possible side effects and particularly of GCs during treatment initiation. The reason given for the latter was the negative connotation of GCs among the general public. However, when participants felt the beneficial effects of the medication, their anxiety about possible actual side effects of the treatment diminished (quote \( t_1-P19 \)). In contrast to the prominent concerns about GCs, some participants

### Table 4

Examples of comment transcripts of participant experiences with intensive combination-treatment strategies.

| Concerns and feelings about ICTS-GCs | "In the beginning you are scared to take so many pills, but when you see that it helps, yes, then you get over it quickly (\( t_1-P19 \))."
|                                      | "You are a bit scared of it because they [the consulted information source on methotrexate] say it is actually a mild form of chemo. Then you think ‘What have I begun?’ (\( t_1-P01 \))."
|                                      | "I feel, or felt, not anymore, a sort of guinea pig. ‘We [the healthcare team] are going to try this and if it does not work after 6 weeks we are going to try that’ (\( t_1-P11 \))."
| Information needs and sources        | "I checked on the Internet if you can do something about your diet because they mention very little about it, which is unfortunate (\( t_1-P07 \))."
|                                      | "I looked up some statistics [about future prospects] but for me it was the same as reading the drug information leaflet, I immediately turned off my computer (\( t_2-P22 \))."
|                                      | "They say: ‘You have arthritis’, but you do not know what it is. And this information [the DVD] is at that moment actually sufficient (\( t_2-P26 \))."
| Relationship with healthcare professionals | "These people went to school, I am a carpenter, they will know nothing about carpentry and I don’t know anything about medication (\( t_1-P09 \))."
|                                      | "I think that it is actually good that they approach it globally and not just the rheumatism. Having people you can ask any question to, I think it makes much sense that you have that opportunity. That they look at all aspects, which is important (\( t_1-P13 \))."
| Self-management in daily living      | "It has become a routine. I get up, take pills, and eat at the table and that is it. In the beginning it was quite difficult to have breakfast if you never did it before, but now it is a routine (\( t_2-P21 \))."
|                                      | "I have every tablet that I have to take in reserve in my bag in case I forgot to take it at home. Then I can still take it at work (\( t_2-P19 \))."
|                                      | "Maybe that is my problem, I feel nothing anymore so then I do not realize why I am taking the pills (\( t_2-P23 \))."
explained that they became reluctant to take MTX only after seeking and gaining information (quote t1-P01). At t2, participant perceptions of the individual drugs remained the same as at t1. The number of pills to be taken raised concerns about long-term health consequences at both t1 and t2. In a few cases, some participants said that they were not necessarily reluctant to take a large number of pills if the effects were beneficial. Some participants stated that a crucial moment of confrontation was the first time they went to the pharmacy for medicaments and saw how many they had to take. The sudden, vivid confrontation with the need of doing this on a regular basis made them feel unhealthy and dependent on medication. At t2, most wanted to minimize the medication intake and said it was reassuring to know at treatment initiation that the medication would be tapered down. At t2, they were glad that they had to take only a little medication. Some still wondered at t2 if they would ever be able to stop taking medication. At the same time, during tapering of medication, many were worried to re-experience flares. Participants with a treatment failure were fearful and doubted the effectiveness of the treatment at t2 (quote t2-P11).

3.2. Information needs and sources

The oral information as well as the informative brochure and the DVD provided at treatment initiation in the CareRA information package triggered a sense of recognition and tackled most of the important questions that the participants were dealing with at treatment initiation. At t1, they wanted more information about the medication and its possible side effects, nutrition, and/or physical activity (quote t1-P07). The need of more information differed among individual participants and changed over time. At t2, they said they worried more about their future prospects and the cause of their chronic condition (quote t2-P22). Certain information needs persisted over time. Some participants wanted at both t1 and t2 more information about their disease evolution and additional therapeutic solutions. For example, some wanted to consult other healthcare professionals or to find helpful tools. Interestingly, at t2, some participants mentioned that they only used the CareRA information package at treatment initiation (quote t2-P26). Not all the participants sought additional information, and some ended their search quickly because they did not want to be confronted with the information or did not know which sources of information were reliable (quote t2-P22).

The sources of information most commonly used were the healthcare professionals, relatives, and the Internet (quote t1-P07).

3.3. Relationship with healthcare professionals

At t1, many participants stated that, during treatment initiation, they felt that they had no option other than to start treatment and passively take the advice of a rheumatologist, whether the rheumatologist was working with a nurse or not. The most important reason for taking the healthcare professionals’ advice was trust in his/her expertise (quote t1-P09). At both t1 and t2, trust was said to be a key element in any relationship between a patient and a healthcare professional. In addition to trust, several participants needed reassurance during treatment initiation and at t1 because of their reservations about ICTS-GCs. At t1 and t2, most participants were very satisfied about their relationships with their healthcare professionals, even when the treatment failed. The participants appreciated the regular follow-up for the reassurance it provided. In addition, involvement in their care was pointed out as being important for the participants, and at both t1 and t2 they said that they were content to be involved in consultation when treatment decisions needed to be made. Several participants were appreciative, especially at t1, when healthcare professionals other than the rheumatologist were involved in their care (quote t1-P13).

Since participants experienced their rheumatology team provided a strict follow-up, many did not perceive, even at t2, the need to involve their family physician in the early phase of ERA care.

3.4. Self-management in daily living

While some participants were overwhelmed by the number of medicaments to be taken, most of them said, at t1 and t2, that they never had difficulty with the combination scheme. The written medication scheme was considered helpful in managing their medication intake during treatment initiation and at t1. The medication scheme also gave participants insight into their further medication intake. Other helpful tools that participants used at t1 to assist their medication intake, not provided in the CareRA information package, were a pillbox, a tray, a calendar, an alarm, and/or back-up medication that they carried with them. Several participants also said that they received assistance from a third party such as a partner. Participants who were previously not used to having breakfast were now confronted with the necessity of eating in the morning, which was associated with taking medicaments. This was generally perceived as the only change in daily life (quote t1-P21). Most participants mentioned that within a few weeks after treatment initiation, they realized that it had become a routine, by associating pill-taking with activities of daily living, such as drinking coffee in the morning (quote t1-P21). The participants got used to taking their medicaments and then developed new coping and self-care skills. For example, they shifted the day of MTX intake or found a way to make up for the forgotten pills as soon as possible. The integration of the ICTS-GCs into the participant’s daily routine and the use of tools persisted at t2 (quote t2-P19). Most participants also mentioned trying additional forms of treatment, such as infrared therapy cabins, essentially at t2. Some participants had difficulty complying with their intake schedules on the days they had to take multiple pills or on the days when their normal daily routine was interrupted. They said that a possible reason for overlooking their medication was the feeling of being healthy again (quote t2-P23).

4. Discussion

4.1. Conclusion

Using a longitudinal qualitative study, we identified themes of patients’ experiences with ICTS-GCs during the early phase of treatment. Firstly, beliefs about ICTS-GCs changed positively over time. Initially, patients’ main concerns were side effects. Afterwards, concerns diminished when the treatment effects were beneficial or expected side effects did not materialize. Secondly, participants commented on the need for information about various topics at both times. The healthcare professionals were the main source of information. Thirdly, participants stressed the need of confidence in healthcare professionals in order to take their advice, especially in the first months of treatment. Lastly, participants used a wide range of self-management strategies at both times. Although several studies have reported experiences of patients with long-term disease, to the best of our knowledge, our study is the first to describe patients’ experiences in the early phase of treatment. In addition to patient experiences, we are currently investigating the content and dynamics of patient-preferred outcomes specifically in the early course of treatment [39]. As in other studies, patients in the present study were mainly concerned about side effects [15,16,24–26]. We found that at treatment initiation concerns essentially focused on expected side effects of GCs. Morrison and colleagues found that 68% of patients with RA were not willing to start oral GCs [24]. However, our study findings showed that when the effects were beneficial or
expected side effects did not materialize, most concerns disappeared already a few months after treatment initiation. In line with patients with long-term disease, patients wanted to be involved in their treatment and information needs differed among patients and could change over time [27–30]. Typically for patients with a chronic condition such as RA is that they wished to make their own decisions about everyday health problems and wanted additional help with self-management activities to relieve symptoms and side effects [29–31]. Apparently this occurred already in the early phase of treatment. Looking for self-management strategies and the interest in complementary medicine started quickly after treatment initiation and appeared to continue during the later treatment phase [31,32].

In contrast to rheumatologists and nurses participating in the CareRA trial, who were more reluctant to use an ICTS-GCs if they were convinced their patients preferred not to take large doses of GCs or different drugs, patients cared about the number of pills they had to take, but not about the dosage or the variety of drugs [9]. Knowing that the drugs would be tapered down later was considered important, as has been shown before [16,25,33]. However, once medication was tapered down, the patients’ feelings were mixed. On one hand, they were happy to take less medication. On the other hand, they appeared to be worried that their original rheumatic complaints would recur. Information needs of patients in the early phase of treatment could explain the required time investment healthcare professionals experienced for patient education [9]. Similar to healthcare professionals’ experiences, a good relationship and trust was considered important [9]. Previous studies showed that a good healthcare professional–patient relationship is associated with treatment satisfaction and adherence [34,35]. Trust is a key component of the relationship between the healthcare professional and the patient, as is patient involvement in treatment decision-making.

4.2. Study limitations and strengths

One limitation is that the participants were not interviewed at treatment initiation because of practical limitations. This means that the data concerning treatment initiation were not provided at the moment itself, but a few months later. Although there could be some recall bias, we judged that 4–6 months was a short enough time for the participants to be able to recapitulate their experiences. A potential limitation of this study is the different interview method used at both times causing that not all patients participating in the individual interviews were willing to participate in the focus groups. As a consequence the patient sample differed slightly at t1 and t2. It is possible that experiences from the patients who agreed to participate in focus groups were different from the patients consenting only to participate in individual interviews. We can of course also not exclude that patients treated outside a trial could have different experiences. However, conducting this qualitative study embedded in the CareRA trial provides an important strength.

Our study has four strengths. First, conducting our longitudinal qualitative study of patient experiences with ICTS-GCs embedded in a clinical medication trial and rooted in daily practice ensures that the ICTS-GCs are applied according to the trial protocol based on treatment recommendations. This is an important strength of this study. Second, we purposively selected patients to ensure a diverse sample to obtain patients experiences. One patient who decided to discontinue treatment was included, but this could reflect daily clinical practice [36]. Third, by adopting a longitudinal approach we have been able to track how patient experiences change over time in an area where other studies used cross-sectional designs. Interview data from two specific times provided a broad, contextualized view of patient experiences that could differ over time because of the gradual treatment changes inherent to the remission induction step-down approach. Fourth, to validate our findings, we used peer debriefings with one rheumatologist and one independent patient researcher in addition to the debriefings with the analyst researchers. The personal experiences of the patient researcher and the rheumatologist helped the analyst researchers to understand the interviewee’s story.

4.3. Practice implications

Understanding the experience of using a prescribed ICTS-GCs from the perspectives of patients could help healthcare professionals in patient education about embarking on an intensive medication scheme. Moreover, it could help other patients to make decisions about their own treatment needs. As treatment progressed, patients’ concerns shifted from the treatment and its immediate side effects to long-term health consequences and experiencing of flares. In preparing for treatment initiation, taking time for patient education that is tailored to individual needs and concerns appears to be a prerequisite in the on-going process to gain patient trust and provide reassurance. Any ICTS-GCs requires a large time investment before and during treatment initiation, to prepare patients for the impact of the treatment. Therefore healthcare professionals can help to allay patients’ concerns by explaining the efficacy and safety of GCs and MTX at treatment initiation and by emphasizing that medication can be tapered down without loss of efficacy later. Apart from the indispensable face-to-face contact with healthcare professionals, another approach for improving patient acceptance of ICTS-GCs is providing information in different formats such as written, audio-visual, and web-based forms. This enables patients to quickly get answers to frequently asked questions, to obtain advice adapted to their personal lifestyle, and to identify whom to contact for further assistance when necessary. Even if patients’ concerns and information needs appear mainly during treatment initiation, our study findings emphasize the role of healthcare professionals during all of the treatment phases. Healthcare professionals involved in treating ERA should be aware that they are the most important source of information for patients in the early phase of treatment. Furthermore, healthcare professionals need to create a relationship of trust, they should involve patients in treatment decision-making, and guide them in self-management strategies. A pragmatic effectiveness trial should be performed to enable professionals to provide such patient centered care and to determine whether this improves recommended ICTS-GCs use in daily practice [37,38].

Funding

The CareRA study is funded by IWT Flanders (Agency for Innovation by Science and Technology). Patrick Verschueren is the holder of the Pfizer chair for early rheumatoid arthritis management at the KU Leuven and is supported by the Clinical Research Foundation, Leuven University Hospitals, Leuven, Belgium.

I confirm all patient/personal identifiers have been removed or disguised so the patient/person(s) described are not identifiable and cannot be identified through the details of the story.

Conflict of interest

The authors have no conflicts of interest to declare. All authors took part in planning, conducting, and/or reporting the qualitative research.

Acknowledgments

The authors thank all the rheumatologists and nurses who gave us access to their patients and all the patients who participated.
References


