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## Promoting physical activity in patients with rheumatoid arthritis

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# Chapter 7

## Implementation of a physical activity intervention for people with rheumatoid arthritis: a case study

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## **Abstract**

**Objective.** A 12-month Internet-based physical activity intervention, including weekly personal feedback from a physical therapist by e-mail and the use of a bicycle ergometer, proved to be effective in a randomised controlled trial concerning sedentary patients with rheumatoid arthritis (RA). The aim of this case study was to investigate potential facilitators and barriers regarding the implementation of this intervention on a larger scale.

**Methods.** Assuming a central delivery of the intervention by 2 trained physical therapists in 4 regions in the Netherlands, the following activities were employed: the recruitment of potential participants (RA patients), the acquisition of co-operation from referring rheumatologists, and the acquisition of reimbursement from regional health insurance companies. Evaluation was done by means of the RE-AIM (Reach, Evaluation, Adoption, Implementation, and Maintenance) framework, of which the following three dimensions were considered relevant: Reach (the number of potential participants), Adoption (readiness for adopting the programme in real life among rheumatologists) and Implementation (the extent to which the intervention could be delivered as intended). Evaluation measures comprised a postal survey among 927 patients with RA in two regions, a telephone survey among rheumatological centres in 4 regions and consultations with 5 regional health insurance companies.

**Results.** 76 out of 461 responding RA patients (20%) met the original study inclusion criteria (being sedentary and having access to the Internet) and were interested in participation. However, the potential costs of the purchase of a bicycle ergometer and the interference with patients' current physical therapy were obstacles for eligible patients to actually participate. Rheumatologists in four out of five rheumatological centres were willing to participate. All five health insurance companies were willing to reimburse the guidance and feedback by the physical therapist and the costs of the internet site (estimated costs € 271,- (£182,-) per patient per year), but not the bicycle ergometer (estimated costs € 350,-), provided that current physical therapy would be discontinued.

**Conclusions.** Facilitators for the implementation of an Internet-based physical activity intervention were the observations that a considerable proportion of RA patients were eligible and interested in the programme, the majority of rheumatologists were willing to refer patients, and health insurance companies were willing to partially reimburse the intervention. Barriers were the additional costs for patients and their unwillingness to discontinue current physical therapy.

These findings underscore the need for additional research into barriers for participation in physical activity interventions among patients with RA, and in reimbursement strategies in particular.

## **Introduction**

Over the past decades, many studies have demonstrated the effectiveness and safety of exercise and physical activity interventions for patients with chronic arthritis (1–3). The currently available evidence is mainly based on clinical trials, executed under controlled research conditions. It is however conceivable that real-world conditions interact with or moderate the impact, accessibility, reach, or sustainability of physical activity interventions (4;5). Indeed, a number of studies have demonstrated the difficulties of translating evidence-based intervention protocols into clinical practice in general (6;7).

Within the field of arthritis research, the knowledge regarding the implementation of evidence-based physical activity interventions in real life is limited. So far, three papers are available in which process and/or outcome data regarding the actual implementation of an exercise or physical activity intervention for people with arthritis on a larger scale than the scale of a (controlled) trial setting were presented (8–10). Domaille et al (10) investigated whether a physiotherapy programme for the management of knee osteoarthritis (OA) could be successfully implemented into clinical practice. The authors compared the outcomes of the implemented programme with those reported in four clinical trials, which used similar interventions and evaluation tools. The implemented programme appeared effective in reducing pain, stiffness and disability. It was concluded from this study that the knee OA programme could be successfully implemented. De Jong et al (11) assessed the feasibility and effectiveness of two exercise and health education programmes for people with OA of the hip and knee within real-life conditions. The programmes were implemented in four regions in the western and central parts of the Netherlands. Both programmes appeared effective in reducing pain, whereas the knee programme was also found to improve OA knowledge and self-efficacy. In neither of these programmes an improvement of mobility was seen. As the outcomes observed in the implementation study were similar to those obtained in the original randomised controlled trials they were based on, it could be concluded that both programmes appear to have ecological validity (12). Boutaugh (8) reviewed the effectiveness of the implementation of two physical activity programmes for people with arthritis: an on-land exercise programme called People with Arthritis Can Exercise (PACE) (13) and an aquatic exercise programme called the Arthritis Foundation Aquatic Program (AFAP) (14). In total, 9 studies which investigated the effectiveness of the PACE and AFAP programmes within real-life community settings were reviewed. The results of the review showed that both

programmes were effective with respect to improving self-efficacy, physical and psychosocial functioning. It was however not reported whether the outcome data regarding the effectiveness of the implemented programs were comparable with effectiveness data collected under more controlled conditions. With respect to the process evaluation, two main problems were reported: lack of quality control and low participant utilisation. In addition to these three papers, Van der Giesen et al (15) reported the preliminary results of a study on the implementation of intensive group exercise therapy for patients with RA. Recruitment and training of providers, the co-operation of rheumatologists and nurse specialists, and reimbursement by health insurance companies in four regions in the Netherlands were successfully accomplished, but patient recruitment did not meet expectations.

In addition to the literature evaluating actual implementation of physical activity interventions in arthritis, a number of studies have been investigating *potential* barriers and facilitators, without actually performing the implementation. A number of studies have demonstrated that disease specific characteristics, such as pain, stiffness, fatigue, and mobility problems, highly influence physical activity behaviour of patients with arthritis (16–20). In addition, socio-demographic and psychosocial factors such as age, gender, education, social support, perceived benefits, and self-efficacy were found to influence arthritis patients' decision to engage in physical activity or exercise (21–25). Moreover, Iversen et al. (26) have demonstrated that rheumatologists' beliefs about the effectiveness of various forms of exercise play an important role in the promotion of physical activity and exercise behaviour among patients with RA.

In almost all studies in which (potential barriers for) the implementation of physical activity interventions was evaluated, a theoretical framework guiding these evaluations was lacking. Probably an important reason for low usage of theoretical frameworks is their limited availability, especially of those frameworks that are explicitly designed to evaluate the implementation of health promotion interventions. The one framework that is available (27), comprises 5 dimensions: Reach, Efficacy, Adoption, Implementation, and Maintenance (RE-AIM). The RE-AIM model can be used to systematically consider the strengths and weaknesses of an intervention in order to evaluate its potential for implementation (28). Reach is defined as the percentage of potentially eligible participants who will take part in an intervention, and how representative they are of the population from which they are drawn. Efficacy or effectiveness concerns both the intended results of an intervention, as well as possible negative or unintended consequences on quality of life and related factors. Adoption refers to the participation rate and representativeness

of both the setting (e.g., worksites or medical offices) in which an intervention is conducted and the intervention agents (e.g., physicians or health educators) who deliver a programme. Implementation refers to the extent to which various components of an intervention are delivered as intended. Finally, the Maintenance dimension includes both individual and setting levels. At the individual level, it refers to the long-term results of intervention, defined as a minimum of 6 months following the last contact. At the setting level, maintenance refers to the extent to which organizations will continue an intervention or programme once a study or initial trial is completed. Both Estabrooks (29) and Dzewaltowski (4) have successfully demonstrated how to apply the implementation of the RE-AIM model when evaluating physical activity interventions. Table 1 describes the questions that should be addressed in order to evaluate physical activity interventions according to the above-mentioned five dimensions.

Based on the principles of the RE-AIM model, this paper aims to describe the results of a case study investigating the potential barriers and facilitators regarding the implementation of an Internet-based physical activity intervention for patients with rheumatoid arthritis (RA), which proved to be effective in a randomised controlled trial.

## **Methods**

### **Intervention description and implementation aims**

The effectiveness of an individually supervised Internet-based physical activity intervention was established in a randomised controlled trial among 160 patients with rheumatoid arthritis (RA) (30). In this trial, in which two 52-weeks Internet-based physical activity programmes were compared, the following inclusion criteria were applied: RA according to the 1987 American College of Rheumatology criteria for RA (31), not being physically active for 30 minutes in succession on a moderate intensity level on at least 5 days a week, in possession of a computer with internet facilities, being able to cycle on a bicycle ergometer, and being interested in a study on a physical activity programme. Half of the patients were randomly assigned to a home-based physical activity programme, delivered through the Internet, with individual supervision by a physical therapist (Individualized Training; IT). In this programme, individual physical activity schedules were offered weekly by means of a password secured website, patients received a bicycle ergometer on loan and had access to an online discussion forum and 3-monthly group sessions. The other patients were randomised to a password secured website with general

information on physical activity and arthritis (General Training; GT). It was concluded that the IT intervention was more effective with respect to increasing the amount of physical activity than the GT intervention (30).

**Table 1.** Definitions and corresponding evaluative questions across the RE–AIM dimensions (29)\*

Dimension	Conceptual definition	Recommended evaluative questions
Reach (Individual level)	The proportion and representativeness of the individuals who participate in the intervention.	Who is eligible and reasons for criteria? Who is excluded and reasons for exclusion? What is the total number of potential participants? How many decline participation? How many were not contacted? How many agree to participate? How many actually participate? What is the participation rate (participants/ potential participants)? Are the participants similar to eligible non-participants on basic demographics and primary outcomes?
Efficacy (Individual level)	The degree to which the level of physical activity of the study participants is changed	Did physical activity change? Were there adverse effects?
Adoption (Setting level)	The proportion and representativeness of the settings, organizations, or agents that use the intervention	What organizations are eligible and reasons for criteria? What is the total number of potential organizations? How many decline participation? How many were not contacted? How many agree to participate? How many actually participate? What is the adoption rate (participating organizations/ potential organizations)? Are the participating organizations similar to eligible nonparticipating organizations on basic resources?
Implementation (Setting level)	The level of fidelity to the intervention's protocol	To what extent were the various intervention components delivered as intended (in the protocol)? What was the timeliness of delivery? Was the protocol adapted? To what extent did the participants receive the intervention components? To what extent did the participants enact the intervention components?
Maintenance (Individual and setting level)	The level of sustained use of the intervention at the organizational level and the sustained participation in physical activity at the individual level	Individual level: What were the long-term effects (minimum in 6–12 months following intervention)? What was the attrition rate? Organizational level: To what extent were different intervention components continued or institutionalized? Was the original program modified?

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After completion of the trial an extension study, in which potential barriers and facilitators regarding a larger scale implementation of the above-mentioned IT intervention were investigated, was set up. Information about these barriers and facilitators was needed in order to be able to decide whether an actual implementation of the intervention would or would not be feasible. The purpose of the extension study, which was set up as a case study, was to have 200 eligible patients with RA being able to participate in the one-year IT intervention in four different regions in the Netherlands: eastern Gelderland, eastern Utrecht, Northern Brabant, and central Zuid-Holland.

### **Preparatory activities**

Regarding the organisational structure, based on the nature of the intervention and the number of patients to be treated, two physical therapists delivering the intervention would be sufficient. These providers would all operate from one location (Leiden University Medical Centre), and visit the patients for initial assessments and group meetings in the four regions.

An advisory board was appointed, consisting of two rheumatologists, a representative of the national arthritis patient organization ('Reumapatiëntenbond'), the Dutch Arthritis Foundation ('Reumafonds'), the Netherlands Organization for Health Research and Development ('ZonMw'), and two other experts in the field of physical activity for patients with arthritis. The four regions were selected in consultation with the advisory board, including thinly as well as densely populated regions. Subsequently, the corresponding rheumatologic centres and rheumatologists were identified.

A standardized provider intervention manual was developed describing the translation of original intervention into implementation in the four regions. Furthermore, in consultation with an econometrician, a cost analysis of the Internet-based physical activity intervention was made. The annual costs were estimated at € 271,- (£182,-) per participating patient (initial assessment, composing weekly physical activity schedules, sending and answering weekly e-mails, occasional telephone contacts, organizing a maximum of 4 group meetings per group in every region, updating the website, sending newsletters). To estimate the costs of the bicycle ergometer, three suppliers of bicycle ergometers were approached. The minimum price for a bicycle ergometer that would suit the quality demands for participation in the physical activity intervention and usage by arthritic patients was € 350,- in case of purchase, or € 30,- per month in case of a lease construction.

### **Evaluation framework**

The case study was conducted according to the principles of the RE-AIM model. Although the RE-AIM framework was originally developed to evaluate actual implementation processes, in the present study it was used to systematically identify potential barriers and facilitators regarding the future implementation of an Internet-based physical activity intervention for patients with rheumatoid arthritis (RA). As this study did not concern an actual implementation process, the dimensions 'Efficacy' and 'Maintenance' were not considered relevant for the analysis. Therefore, the results of the case study are described according to three dimensions of the RE-AIM model: Reach, Adoption and Implementation.

## **Results**

### **Reach**

In order to determine which proportion of patients with RA would be potentially eligible for participation in the physical activity intervention, a short questionnaire was sent to 927 RA patients from two rheumatology outpatient clinics, situated in 2 of the 4 selected regions (Northern Brabant and central Zuid-Holland). Two rheumatologists working in these outpatient clinics provided the registries of RA patients who had been visiting their outpatient clinic in the past 15 months. The registries contained names and addresses of the patients and were sorted in ascending order by the date of their forthcoming visit to the outpatient clinic. The questionnaires were sent by postal mail together with a letter explaining the aim of the study and a response envelope. It was decided to first wait for the results of the two selected regions, before sending the questionnaires to the patients from the other two regions.

In total, the questionnaire contained 10 questions. The first 5 questions concerned the same five initial inclusion criteria as employed in the original study: availability of a computer with Internet facilities, being able to use Internet and e-mail, not being too physically active, being able to cycle on a bicycle ergometer, and being interested in participation in an Internet-based physical activity program. Two other questions evaluated patients' current participation in physical activity or exercise interventions. To be able to further define the potential reach of our intervention, the final questions included in the questionnaire evaluated the patients' willingness to invest in a bicycle ergometer. First, it was evaluated whether or not patients were already in possession of a

bicycle ergometer. Then, patients were asked how much money they would be willing to spend on a new bicycle ergometer if they did not possess one. The questions comprised their willingness to pay both when it concerned once only costs as well as when it concerned a lease construction with monthly costs.

461 patients sent back the questionnaire (response 50%). Data on (socio-demographic) characteristics of the patients who did not send back the questionnaire are not available. Table 2 shows the proportions of patients fulfilling the above-mentioned inclusion criteria. Seventy-six (20%) patients fulfilled all 5 described criteria. Furthermore, the results of the questionnaire showed that 121 patients (27%) currently participated in any form of physical activity intervention or exercise therapy. Of these patients, 30 (25%) were willing to give up these interventions or therapy in order to switch to the Internet-based physical activity intervention. When the other 5 initial inclusion criteria were also taken into account, the results showed that of the 76 patients who fulfilled these criteria, 17 (22%) participated in any form of physical activity intervention or exercise therapy and 3 of these patients (18%) were willing to give up these activities.

132 patients (29%) possessed a bicycle ergometer. Additional information about the type and quality of this ergometer was not gathered. Table 3 shows the results of the patients' willingness to invest in a new bicycle ergometer in order to participate in the intervention (if they did not already possess one). In total, 13 (5%) and 24 patients (8%) would be willing to invest the required amounts of € 350,- in case of purchase or € 30,- per month in case of leasing, respectively

**Table 2.** Number (%) of patients with RA who fulfil the inclusion criteria for participation in the study on the implementation of an Internet-based physical activity programme (n=461)

Inclusion criterion	Number (%)
In possession of computer with Internet facilities	276 (60)
Being able to use Internet and e-mail	248 (55)
Not being physically active for 30 minutes in succession on a moderate intensity level on at least 5 days a week	225 (53)
Being interested in participation in an Internet-based physical activity program	158 (36)
Being able to cycle on a bicycle ergometer	381 (84)
Fulfilling all of above-mentioned criteria	76 (20)

**Table 3.** Number (%) of patients who are willing to pay various amounts of money for a new bicycle ergometer required to participate in an Internet-based physical activity intervention

Once only amount		Monthly amount	
Nothing	182 (62)	Nothing	179 (62)
€ 1 to € 150,-	64 (22)	€ 1 to € 15,-	87 (30)
€ 151,- to € 300,-	37 (12)	€ 16,- to € 30,-	23 (8)
€ 301,- to € 450 ,-	11 (4)	€ 31,- to € 45,-	1 (0)
€ 451,- to € 600,-	2 (1)	€ 46,- to € 60,-	0

### Adoption

This study took place within the Dutch health care setting. Within this setting, the following subsettings were considered relevant: A. Rheumatologic centres, including referring rheumatologists. B. Health insurance companies and C. The providers of the intervention, i.e. physical therapists. As for this particular intervention, building on the structure proven to be successful in the original RCT (30), only two physical therapists would be needed, who would operate from one location, it was considered not relevant to incorporate this subsetting as well.

We selected four rheumatologic centres in the four regions. Subsequently, 4 rheumatologists, each representing one rheumatologic centre and one region, were contacted by telephone. They were sent additional information about the intervention and implementation study by e-mail. One rheumatologist declined participation, so that another rheumatologist from another rheumatologic centre in the same region (central Zuid-Holland) was approached. In total, thirteen rheumatologists were connected with the final four rheumatological centres who were willing to participate.

The primary investigator (MvdB) visited all 4 representing rheumatologists to further discuss the practical details of the implementation process and in one outpatient clinic a presentation was given to all staff members of the rheumatology department. Eventually, all four rheumatologists appeared enthusiastic about the implementation plans and agreed to co-operate.

Because the Internet-based physical activity intervention was to be implemented within the Dutch health care setting, the willingness of health insurance companies to partially or fully reimburse the intervention was examined. The Internet-based physical activity intervention was a new intervention for which a defined insurance reimbursement structure was not yet available. Five representatives from five large health insurance companies operating in the four targeted regions

in the Netherlands were approached. All agreed to reimburse the direct costs of the physical activity intervention, but not the costs of the bicycle ergometer. Furthermore, reimbursement of other forms of individual or group exercise therapy simultaneously with the Internet-based physical activity intervention would not be permitted.

### **Implementation**

As reimbursement by the health insurance companies could only be partially realised and the patients' willingness to pay was limited, potential adjustments to the original intervention were discussed during two meetings with the advisory board. The participants of this meeting all agreed that, if the implementation of the Internet-based intervention would be obstructed because of lack of financial resources, the bicycle ergometer could perhaps be replaced by other, less expensive, exercise equipment and/or other physical activities. For example, the main activity of cycling on a bicycle ergometer in the original intervention could be replaced by the activity walking outside (32). If the intervention indeed would switch to a primarily walking-based program, the advisory board recommended the provision of a pedometer (33;34).

As not many patients appeared to be willing to give up their current therapies in order to switch to the new physical activity intervention, the advisory board discussed the possibility of offering the physical activity intervention outside the Dutch health care system. However, in this case, individual supervision by the physical therapists could no longer be provided.

In general, it was discussed that the disadvantage of incorporating large modifications to the contents of the intervention, such as switching to a walking-based programme or leaving out the individual supervision, is that one can no longer build on the proven scientific efficacy.

Moreover, it was discussed how to control and monitor the quality of the intervention. It was decided that only certified providers would be allowed to offer the intervention. In order to facilitate the certification process of these providers, the development of a quality mark and formal registration of this quality mark would be needed. In addition, regulations regarding the initial training and continuous education of the providers would have to be formulated. During the course of the study, a number of organisations showed interest in taking a leading role in the future organisation and quality assurance of the intervention, however no decision was made. Drawbacks in the discussion included potential competition among different organisations currently involved in the education and training of physical therapists and possible competition among "general" and "specialised" primary physical therapists. It was decided to further explore

this issue with the physical therapists' professional organization and the Dutch Arthritis Foundation.

## Discussion

There is a large body of evidence regarding the effectiveness and safety of exercise or physical activity interventions for people with arthritis. However, little is known about to what extent these evidence-based interventions are feasible, accessible and sustainable and remain effective when they are translated into daily clinical practice. The results of our case study showed that possible barriers and facilitators regarding the implementation of our evidence-based Internet-based physical activity intervention could systematically be analyzed by using the RE-AIM model. Cooperation of rheumatologists and the concerning rheumatologic centres appeared to be feasible. However, the survey among RA patients showed that the final number of patients who would actually participate would be low.

One main barrier for implementation on a larger scale appeared to be the funding of the physical activity intervention. In the Netherlands, as of January 2006, there is a single statutory basic healthcare insurance policy for everyone. Statutory basic healthcare insurance covers the cost of basic medical care. In addition, healthcare insurers offer supplementary packages to cover the cost of additional healthcare which may, or may not include reimbursement of individual or group exercise therapy. Although in our study, the insurance companies were willing to reimburse the direct costs of the intervention (i.e. the costs regarding the supervising physical therapists), neither these insurance companies nor the patients were willing to invest in the required exercise equipment (i.e. the bicycle ergometer). Problems regarding the reimbursement of health promotion interventions when implemented on a larger scale have been reported before. In Australia a major obstacle for the implementation of the "SNAP" approach (a programme for the management of 4 behavioural risk factors: Smoking, Nutrition, Alcohol and Physical activity) into general practice was the lack of a funding model (35). Another barrier observed in the present study was the participants' limited willingness to give up their current individual or group exercise therapies in order to switch to the new physical activity intervention. Health insurance companies would not reimburse two different therapies or interventions simultaneously. As stated above, individual or group exercise therapy is to a large extent reimbursed for people with arthritis in the Netherlands, whereas for the proposed intervention a financial contribution from

the patients themselves would be needed. The discussion on to what extent patients with arthritis have, like healthy people, their own responsibilities regarding the acquirement of sufficient levels of physical activity is in the Netherlands still in its initial stages. With this discussion, the fact that a chronic disease in general places a large burden on the individual's financial situation always needs to be taken into account. Apart from the additional costs associated with their switch to another intervention, satisfaction and habituation with current physical or exercise therapy may also have played a role.

In order to make a future implementation of the Internet-based physical activity intervention possible, several possible adjustments to contents of the programme have been discussed, such as leaving out the rather expensive bicycle ergometer or offering the intervention without the individual supervision by the physical therapist. However, these adjustments would introduce the disadvantage that one can no longer build on proven effectiveness of the original program. Although it has been established that this so-called process of re-invention can take place without hampering successful implementation of interventions (36), it can also fail the dissemination process if the key components of an intervention are changed (37). Future research should further investigate whether the advantages of making the programme adjustments outweigh the disadvantages of these re-inventions.

When interventions are implemented on a larger scale, it is important to be able to control and protect the quality of these interventions. Indeed, within the Implementation dimension of the RE-AIM model it is to be evaluated to what extent the participants received the intervention components as intended. In this study a standardized provider intervention protocol to decrease the risk of violations to the intervention contents was developed. Furthermore, discussions on the registration of a quality mark for the delivery of physical activity programs for patients with arthritis were started. A quality mark would imply that only certified providers would be allowed to offer specific interventions to RA patients. Discussions on how this would influence competition among physical therapists in the Netherlands, as well as who is responsible for controlling and managing this quality mark are still ongoing.

A limitation of our case study is the fact that the actual implementation did not take place yet. Therefore, the dimensions 'Efficacy' and 'Maintenance' of the RE-AIM model could not be taken into account. As a consequence, information about possible adverse effects, as well as the long-term results of the Internet-based intervention and the extent to which organisations will continue to offer this intervention could not be provided. In our study, the health insurance

companies willing to reimburse the direct costs of the intervention for a period of 12 months, however future activities should aim to acquire structural financial commitment. Another limitation was the inclusion of a limited number of patients, from two selected regions. Although the regions were geographically distant, it is conceivable that the results from surveys in other regions in the Netherlands would have differed from the data presented. Moreover, with a response rate of 50%, it cannot be ruled out that in the RA population as a whole the proportion of patients who met the inclusion criteria and were interested in the intervention may differ from the rate observed in the present case study.

In conclusion, this case study on the implementation of an internet-based physical activity intervention showed that lack of full reimbursement and the obligation to stop concurrent physical therapy were major obstacles for RA patients to participate. These are both barriers that have not been extensively addressed in previous studies, but may play a role in physical activity interventions with other modes of delivery as well. As the Internet is a promising medium to enhance physical activity in patients with RA, future activities should focus on exploring other possible ways to achieve structural, partial or total funding for Internet-based physical activity interventions, delivered within or outside the health care system. These efforts would involve inter-organisational partnerships, including patients' representatives, public health agencies, clinical care providers, community organisations, health insurance companies and others (38). Furthermore, complementary qualitative studies should be done in patients with arthritis to investigate in more depth which barriers play a role with respect to switching over to alternative physical activity or exercise interventions and the ensuing financial consequences.

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