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ORIGINAL ARTICLE

# Effects of preventive versus ‘on-demand’ nutritional support on paid labour productivity, physical exercise and performance status during PEG-interferon-containing treatment for hepatitis C<sup>☆</sup>



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## Summary

**Background and objective:** Deterioration of nutritional status during PEG-interferon containing therapy for chronic hepatitis C can be ameliorated by preventive nutritional support. We aimed to explore whether such support also affects paid labour productivity, physical exercise and performance status.

<sup>☆</sup> This study was registered at ClinicalTrials.gov (identifier NCT00841243).

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**Abbreviations:** CHC, Chronic hepatitis C; PEG, Pegylated; SVR, Sustained virological response; RCT, Randomized controlled trial; HCV, Hepatitis C virus; KPS, Karnofsky performance status.

**Methods:** In this prospective randomized controlled trial (J Hepatol 2012;57:1069–75), 53 patients with chronic hepatitis C had been allocated to ‘‘on demand’’ support ( $n=26$ : nutritional intervention if weight loss  $>5\%$ ) or preventive support ( $n=27$ : regular dietary advice plus energy- and protein-rich evening snack) during PEG-interferon-containing therapy. Paid labour productivity, physical exercise and performance status were evaluated at baseline, after 24 and (if applicable) after 48 weeks of treatment.

**Results:** At baseline, 46% of patients performed paid labour and 62% performed some kind of physical exercise. Furthermore, most patients were able to carry out normal activity with only minor symptoms of disease (mean Karnofsky performance score: 94). Decreases of paid labour productivity ( $-21\%$  vs.  $-70\%$ ,  $P=0.003$ ), physical exercise activity ( $-43\%$  vs.  $-87\%$ ,  $P=0.005$ ) and Karnofsky performance scores ( $-12\%$  vs.  $-24\%$ ,  $P<0.001$ ) were less in the preventive than in ‘‘on demand’’ group after 24 weeks of treatment. Effects of preventive nutritional support were even more pronounced after 48 weeks.

**Conclusions:** Preventive nutritional support markedly ameliorates decreases of paid labour productivity, physical exercise and performance status during PEG-interferon-containing treatment for chronic hepatitis C.

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## Introduction

Chronic hepatitis C (CHC) is a leading cause of liver cirrhosis worldwide. Antiviral therapy for CHC has changed strongly over the past few decades and is nowadays highly effective. Until 2012, combined pegylated (PEG)-interferon plus ribavirin was the standard of care for CHC and resulted in a sustained virological response (SVR) in 40–90% of treatment-naïve patients [1–4]. Nevertheless, interferon containing antiviral therapy is associated with significant side effects, which may affect paid labour productivity, physical exercise activity and performance status.

Significant weight loss during interferon-containing antiviral therapy often occurs because of decreased appetite due to fatigue, fever, nausea, depression or taste changes during antiviral treatment [5]. Furthermore, interferon- $\alpha$ -based therapy delays gastric emptying, which could lead to upper abdominal discomfort and less appetite [6]. Average weight loss during treatment is reported to be approximately 7% of basal weight [5,7,8]. Weight loss may be even more pronounced with triple therapy containing protease inhibitors [9]. Severe weight loss during antiviral therapy is accompanied by a catabolic state and protein–energy malnutrition, which is also a frequent phenomenon in advanced hepatic disease [10]. A late-evening protein-rich nutritional supplement induces an anabolic state in patients with advanced liver disease [11]. In a recently published randomized controlled trial (RCT) [7], we found that preventive nutritional advice plus an energy- and protein-rich evening snack before bedtime also prevents deterioration of nutritional status of patients during PEG-interferon-containing antiviral treatment for CHC, with improved digestive symptoms and quality of life. Of note, such nutritional support also prevents catabolic state, as indicated by preserved handgrip strength according to Jamar [12–14], pinch grip strength and other parameters of nutritional state [7].

In previous studies, presence of CHC was associated with less work productivity and more absenteeism [15]. These findings were even more pronounced during PEG-interferon-containing therapy [16–19].

In the current study, we examine the effects of preventive versus ‘‘on-demand’’ nutritional advice plus supplementation on paid labour productivity, physical exercise and performance status during PEG-interferon-containing treatment for CHC.

## Patients and methods

### Patient and clinical characteristics

In a previously published RCT performed in the period 2008–2010, we evaluated potential beneficial effects of preventive nutritional support during PEG-interferon-containing antiviral treatment for CHC on nutritional state and quality of life [7]. Nevertheless, no data on paid labour productivity, physical exercise or performance status have been included in this previous publication. We therefore analyzed data on effects of preventive nutritional support on paid labour activity, physical exercise and performance status. These data had been prospectively collected and were all available in the database of this RCT. In total, 53 patients tested positive for serum hepatitis C virus (HCV)-antibodies and HCV RNA during at least 6 months and with an indication for antiviral treatment [20–22] were randomized for the ‘‘on demand’’ group ( $n=27$ ) or the preventive group ( $n=26$ ). Both groups received PEG-interferon alfa-2b 1.5  $\mu\text{g}/\text{kg}/\text{week}$  subcutaneously and oral ribavirin for 24 or 48 weeks depending on genotype and viral load. Ribavirin dose was 800, 1000, 1200, and 1400 mg/day for body weight  $<65$  kg, 65–75 kg, 76–105 kg, and  $>105$  kg, respectively. Duration of antiviral therapy was  $29 \pm 14$  weeks in the ‘‘on demand’’ and  $32 \pm 12$  weeks in the preventive group ( $P=0.268$ ). Average PEG-interferon  $\alpha$ -2b dosage ( $1.55 \pm 0.23$

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