Heads Up: a pilot trial of a psychological intervention to improve nutrition in head and neck cancer patients undergoing radiotherapy

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Malnutrition in head and neck cancer (HNC) patients is common and associated with poorer radiotherapy outcomes including increased mortality. This pilot trial investigates the feasibility and effectiveness of a psychological intervention to improve nutritional status, depression and mortality in HNC patients undergoing radiotherapy. Fifty-nine intervention patients received motivational interviewing and cognitive behavioural therapy compared to 70 historical controls who received treatment as usual. Participants were assessed for nutrition, depression and mortality. There were no significant differences between groups in nutritional status, depression or mortality. Subgroup analyses among patients at greater nutritional risk (cancers of the oral cavity, pharynx, larynx) revealed a potentially clinically important reduction on the PG-SGA and lower mortality (31% of controls vs. 16% intervention; \( P = 0.03 \)) in favour of the intervention condition. Potential benefits in nutritional status and in mortality in this pilot trial of a psychological intervention among HNC patients at high nutritional risk suggest that a larger randomised controlled trial is warranted.

Keywords: cancer, head and neck, nutrition, psychology, radiotherapy.

BACKGROUND

Head and neck cancers (HNC) are the world’s fifth most common cancers (Ferlay et al. 2015) and have a relatively high mortality rate (Tracey et al. 2008), ranking eighth worldwide (Ferlay et al. 2015). Due to tumour location and the rigours of treatment, HNC patients have a higher
risk of malnutrition than patients with cancer at other sites (Ottery 1996; Lees 1999; Kruizenga et al. 2003).

The consequences of malnutrition in HNC patients include impaired immune function, reduced vitality and increased complications due to treatment side effects [Larsson et al. 2005] and these have been associated with increased mortality [van Leeuwen et al. 1999; Colasanto et al. 2005]. Malnutrition can decrease patients’ functional status, which can result in interrupted or incomplete treatment [Rosenthal 2007]. Even if malnutrition is appropriately treated and radiotherapy is eventually completed, pauses in radiotherapy are associated with poorer outcomes and greater mortality [Robertson et al. 1998; James et al. 2008; Rosenthal et al. 2011]. Therefore, any intervention that assists HNC patients to maintain good nutrition and complete radiotherapy without interruption could be an important addition to their cancer treatment.

The grouping term of HNC encompasses all tumours of the upper aerodigestive tract and its connective structures, which may not all have the same nutritional risk. Studies of HNC subgroups have found greater nutritional risk in HNC cancers of the oral cavity, pharynx and larynx compared to salivary, thyroid and cutaneous tumours [Hammerlid et al. 2001]. This is not surprising as it is unlikely that a patient with a skin cancer on their forehead will face the same nutritional problems as a patient with a tumour on their tongue or throat. Despite acknowledging those at increased risk, current evidence-based guidelines outline the importance of nutritional intervention for all HNC patients [Findlay et al. 2014]. Therefore, the psychological intervention in this pilot trial was provided to all HNC patients while also examining for which subgroup of HNC the intervention was efficacious.

In addition to malnutrition, HNC patients also exhibit relatively high levels of depression and anxiety [de Graeff et al. 1999]. Depression can adversely affect the patient’s ability to cope with the rigours of cancer treatment and may affect nutrition through poorer compliance to dietetic advice [DiMatteo & Lepper 2000; Faller & Schmidt 2004]. A recent study confirmed this association, finding that among HNC patients baseline depression predicted end of treatment malnutrition better than commonly accepted risk factors such as age, cancer stage, gender, presence of a live-in carer or radiation dose [Britton et al. 2011].

Although HNC patients face physical and psychological difficulties, relatively few psychological intervention studies have been conducted among this group [Luckett et al. 2011]. This is surprising given psychological interventions have improved health outcomes in other illnesses including chronic diseases [Lorig et al. 1999], heart disease [Welton et al. 2009] and breast cancer (Scheier et al. 2005). The paucity of psychological intervention studies among HNC patients may be related to the perception that this patient group is more challenging than other groups, with higher incidence of mental health problems, substance use comorbidities and social issues such as homelessness [Kugaya et al. 2000; Moore & Durden 2010]. Thus, tailored interventions may be needed to work effectively with this population.

In addition to tailoring, interventions also need to be evidence-based. Motivational interviewing (MI) is a ‘collaborative conversation style for strengthening a person’s own motivation and commitment to change’ [Miller & Rollnick 2012, p. 12]. Evidence-based reviews of MI have consistently demonstrated MI to be more effective than advice in treating physiological and psychological problems, with a statistically and clinically significant effect observed in approximately 75% of studies [Sune Rubak 2005]. Similarly, cognitive behaviour therapy (CBT) has delivered consistently positive results in nutritional interventions for behaviour change in eating disorders [Ozier & Henry 2011]. A review for the Academy of Nutrition and Dietetics also highlighted that MI coupled with CBT was highly effective in changing dietary behaviours [Spanh et al. 2010].

Psychological interventions have been shown to be effective in alleviating physical illness and MI- and CBT-based interventions have improved outcomes in the context of physical disease and mental illness. Therefore, given HNC patients face higher rates of mental health problems, difficulties associated with side effects of treatment and malnutrition, a MI and CBT intervention has the potential to improve radiotherapy morbidity, radiotherapy compliance/completion and post-treatment mortality.

**Aims**

This pilot trial aimed to examine the effectiveness of a psychological intervention to improve nutrition in HNC patients undergoing radiotherapy. It also aimed to explore for which subgroups of HNC patients the intervention was most efficacious. The primary outcome was nutritional status with depression and mortality considered secondary outcomes.

**Hypotheses**

1. Participants in the intervention condition will have superior nutritional status [lower Patient-Generated Subjective Global Assessment (PG-SGA) scores] at the
end of radiotherapy and in recovery compared to historical controls.

2. Participants in the intervention condition will have lower depression scores at the end of radiotherapy and in recovery than historical controls.

3. Participants in the control condition will be more likely to have died than those in the treatment condition over a 40-month follow-up; and

4. There will be a difference in efficacy of the intervention across HNC tumour sites, with a higher impact on those subgroups that have a higher risk of malnutrition.

METHODS

Subjects

Ethics approval for this study was obtained from the Hunter New England Health Human Research Ethics Committee (08/12/17/5.03) to recruit patients from the outpatient radiotherapy department of the Calvary Mater Hospital, Newcastle, New South Wales, Australia. It was registered with the Australian New Zealand Trial Registry (ACTRN12609000384257). Inclusion criteria required participants to have the capacity to give informed consent, communicate in English, have a diagnosed HNC, be scheduled for radical radiotherapy with non-palliative aims and to be receiving at least 20 fractions of radiotherapy. All patients within a defined period in 2 consecutive years were approached by research staff at the time of their radiotherapy planning scan.

Design

The study compared patients in the intervention condition with an historical cohort of HNC patients recruited in the previous calendar year for an earlier project (Britton et al. 2011) with the same inclusion criteria and assessments. It was estimated that 130 participants in total would provide the study with 80% probability of detecting a clinically important difference of 3 points on the primary outcome of nutritional status on the PG-SGA at the 5% significance level, based on the assumption that the standard deviation was 6.

Assessment intervals

Participants were assessed during the first week of radiotherapy, the last week of radiotherapy and 1-month post-radiotherapy cessation (recovery). Mortality status and date of death were assessed for each participant 40 months after their study enrolment.

Assessments

At each time point, a dietitian conducted the PG-SGA to assess nutritional status. This is considered the ‘gold standard’ in oncology nutrition measurement and consists of a self-report questionnaire and a physical assessment by a dietitian (Bauer et al. 2002), with lower scores indicating better nutritional status. Depression was assessed using the Patient Health Questionnaire-9 (PHQ-9) score, which is a brief screen for depression widely used in oncology (Kroenke & Spitzer 2002), and has previously been shown to be predictive of malnutrition (Britton et al. 2011). Higher scores indicate higher levels of depression. Participants also consented for information regarding their malignancy and treatment to be extracted from their medical records and for a follow-up audit of disease progression.

Intervention

The ‘Heads Up’ intervention was a psychological intervention developed and delivered by a clinical psychologist (BB) as an adjunct to the service provided by the oncology dietitians and introduced as part of the normal multidisciplinary care of HNC patients in the radiotherapy department. Intervention sessions were conducted in the radiotherapy department and were scheduled immediately prior to or following other radiotherapy appointments. The intervention was guided by a manual developed by the researchers [available on request].

The intervention utilised a two-tiered tailored approach. The initial tier was provided to all participants and consisted of two sessions. The first session was conducted in the first week of radiotherapy and the second was provided in the fourth week, when radiotherapy side effects may begin to impact upon nutrition. Both sessions employed MI (Miller & Rollnick 2012) to improve nutritional self-care and compliance with dietary advice. The second session provided an opportunity to reframe the difficulties experienced to further motivate patients to change their nutritional behaviours. Tier-1 sessions also included psycho-education about the possible psychological sequelae of a HNC diagnosis and treatment, and how to recognise and remedy the signs and symptoms of psychological distress, including seeking professional assistance.

Only those patients with moderate or severe depression (based on their baseline PHQ-9 scores) also received a second tier of intervention consisting of brief [10 min] sessions with the clinical psychologist twice a week for the duration of their radiotherapy. During these sessions,
participants received CRT for depression and additional, more intensive MI for nutritional behaviours.

Analyses

Intervention data were compared with historical control data using Stata 11.2 (StataCorp. 2009). Groups were compared at baseline using t-tests (continuous measures) and chi-square tests (categorical measures).

Linear regression mixed models were generated with nutritional status (PG-SGA) and depression (PHQ-9) as the outcome variables in an intention to treat model. As this was a pilot trial exploring small effects in a large amount of noise, unadjusted models and models adjusting for baseline scores were developed. These allowed for an examination of the factors that affected nutritional status and depression, which would not have been evident when baseline score was included.

Nutritional status

A core model was created to describe nutritional status using the factors endorsed by relevant literature: time, tumour site (Hammerlid et al. 2001), tumour stage (Poulsen et al. 2008) and baseline depression (Britton et al. 2011) with the individual as a random effect. Potentially confounding factors were added to the core model including: prescribed radiotherapy dose, use of a nasogastric feeding tube (NGT), use of a percutaneous endoscopic gastronomy (PEG) feeding tube, age, sex and availability of a carer. Finally, the contribution of the intervention condition was added to the model.

Depression

The modelling for this outcome was exploratory. The core model included time and intervention condition and a backwards stepwise elimination was applied.

Mortality data were compared using Pearson's chi-square for the overall difference in mortality. Differences in time to death between treatment groups were examined using Kaplan–Meier survival curves and tested for significant difference using Cox regressions that controlled for differences between the groups in tumour site and stage.

Subgroup efficacy

The same linear regression mixed models, chi-square and Cox regressions for nutritional risk, depression and mortality were conducted, limiting the analysis to those tumours considered to be at high nutritional risk [Hammerlid et al. 2001].

RESULTS

In the study providing the historical control sample, 70 of 92 (76%) eligible patients approached agreed to participate in the study (Fig. 1). The intervention group contained 59 HNC patients recruited from a possible 65 (91%). Radiotherapy treatment protocols remained constant throughout both control and intervention recruitment periods. There were no significant differences between participants and non-participants in either the historical controls or the intervention group in key variables including age, gender, cancer site, stage or radiotherapy prescription.

Of the 129 patients recruited to the study, 120 (93%) completed the end of radiotherapy assessment. Two participants died while on radiotherapy, one ceased radiotherapy because of an adverse skin reaction and six completed radiotherapy but were lost to follow-up. By the post-radiotherapy assessment, another two participants had died and seven were lost to follow-up; resulting in 111 (111/125 = 88%) HNC patients completing all three assessments.

Baseline data

There were no significant differences in baseline malnutrition or depression scores between intervention and control patients (Table 1). There were approximately equal numbers of nutritionally high-risk (oral, pharynx and larynx) versus low-risk tumours (salivary glands and cutaneous) in both conditions (Table 1). All but six participants [intervention = 3, control = 3] had pathologically confirmed squamous cell carcinomas.

Nutritional status – Hypothesis 1

Nutritional status declined significantly [higher scores] over time [end of RT scores presented in Fig. 2]. Baseline nutritional status and baseline depression score were significant predictors in the adjusted and unadjusted models respectively. Neither the core factors of tumour site and stage were significant, nor was the intervention group. None of the non-core factors significantly improved the model and were not included in the final model. Table 2 displays the results from the linear mixed model and the contribution of the predictor variables to the total PG-SGA score across treatment and recovery.
Depression – Hypothesis 2

The second hypothesis predicted that participants in the intervention condition would have lower depression scores at the end of treatment and in recovery compared to historical controls. This was not supported in either the adjusted or unadjusted models. Time [effect size (95% CI)]
CI) = 1.98 [−2.84 to −1.02] P < 0.01, a higher number of radiotherapy fractions completed [ES = 0.21 (0.05−0.37) P < 0.01] and higher baseline depression [ES = 0.51 (0.35−0.67) P < 0.01] were the only significant predictors of later increased depression scores. There was no significant contribution to the depression model of age, sex, tumour site, cancer stage, NGT, PEG or presence of a carer, and these were excluded from the final model.

**Mortality – Hypothesis 3**

Mortality was assessed 40 months post-trial entry for both the intervention and control conditions. Data did not support the third hypotheses that at follow-up more participants in the control condition would have died than in the intervention condition after 40 months. Of the control participants 22(31%) and 12(20%) of the intervention participants had died [Pearson’s chi-square (1) = 2.03, P = 0.15]. A Cox regression model controlling for tumour site and stage found a hazard ratio of mortality of control to intervention of 0.47 [P = 0.051].

**Subgroup analyses – Hypothesis 4**

Subgroup efficacy was assessed by limiting the analysis to only those patients with oral cavity, pharynx and larynx cancers, which are generally considered to be at a higher risk of malnutrition than those with salivary, thyroid and cutaneous HNC (Hammerlid et al. 2001). This is evident in Fig. 2, which demonstrates that on average, salivary and cutaneous cancers were not scored as ‘high risk’ in either condition. Even at the end of radiotherapy, when nutritional status risk scores were highest, this patient subgroup did not generally exceed the PG-SGA score of 9, which indicates nutritional risk (Bauer et al. 2002). The subgroup analysis effectively halved the sample to 38 high-risk participants in the historical control condition and 31 participants in the intervention condition. Table 3 shows that despite the sample size halving, the intervention effect size more than doubled.

The intervention did not improve depression scores when limiting the sample to nutritional risk participants. The same variables were endorsed in the subgroup analysis as in the larger model and again the intervention group did not appear to have significantly reduced depression. It was revealed that 13 of 38 controls (31%) compared to 5 of 31 intervention (16%) patients in the high-risk group had died [Pearson’s chi-square (1) = 2.90, P = 0.09]. Cox regression showed that for high-risk tumour sites over the course of 40 months, control patients were significantly more likely to die than intervention patients when controlling for tumour site and tumour stage [P = 0.03]. Kaplan–Meier survival curves illustrate this difference in Figure 3.

**DISCUSSION**

This pilot study did not find significant differences in nutritional status, depression or mortality between inter-

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Table 2. Linear regression mixed model of nutritional status as measured by PG-SGA

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Adjusted</th>
<th>Unadjusted</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Effect size [95% CI]</td>
<td>P-value</td>
</tr>
<tr>
<td>Baseline malnutrition</td>
<td>0.39* [0.15-0.63]</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Time</td>
<td>5.07 [−6.2 to −3.9]</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Condition</td>
<td>0.71 [−2.8 to 1.34]</td>
<td>0.49</td>
</tr>
<tr>
<td>Tumour site</td>
<td>3.09 [0.14−6.03]</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Stage</td>
<td>2.07 [−1.44 to 5.82]</td>
<td>0.25</td>
</tr>
<tr>
<td>Baseline depression [PHQ-9]</td>
<td>0.12+ [−0.13 to 0.36]</td>
<td>0.35</td>
</tr>
</tbody>
</table>

*Per unit on PG-SGA: Patient-Generated Subjective Global Assessment.
†Per unit on PHQ-9: Patient Health Questionnaire 9.
vention patients and historical controls when considering an entire HNC sample. However, secondary analyses suggested between group differences in nutritional status and revealed significant differences in mortality in the subset of HNC patients at nutritional risk.

**Nutritional status**

The model demonstrated that HNC patients were significantly more malnourished by the end of radiotherapy compared to their first week of treatment. This result is consistent with the literature suggesting that the hardships of radiotherapy are associated with difficulties in adequate nutritional intake (Isenring et al. 2004; Colasanto et al. 2005). The significance of the factor ‘time’ in this case can be seen as a proxy for the effects of radiotherapy on nutrition.

Tumour site, stage and baseline depression were included in the core nutritional status model because of previously established associations with radiotherapy-related malnutrition (Hammerlid et al. 2001; Poulsen et al. 2008; Britton et al. 2011). Interestingly, tumour site and stage were not significant in a model alongside time and baseline nutritional status or depression. That baseline depression predicted end of treatment nutritional status confirms past findings (Britton et al. 2011). That baseline depression was no longer significant when included with baseline nutritional status suggests that there may be a relationship between depression and malnutrition before beginning radiotherapy.

None of these factors were significant when placed in a model alongside the effects of radiotherapy and baseline nutritional status. Intuitively, tumour location would affect nutritional status, but the pilot finding suggests that baseline nutritional status accounted for the pre-treatment differences associated with tumour site, stage and depression.

**Depression**

Depression scores in the intervention condition were not significantly different to historical controls during radiotherapy and recovery. The data did not support the hypoth-

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Adjusted Effect size (95% CI)</th>
<th>Adjusted P-value</th>
<th>Unadjusted Effect size (95% CI)</th>
<th>Unadjusted P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline malnutrition</td>
<td>0.32* (0.15–0.63)</td>
<td>0.06</td>
<td>Reference</td>
<td></td>
</tr>
<tr>
<td>Time</td>
<td></td>
<td></td>
<td>Reference</td>
<td></td>
</tr>
<tr>
<td>End of treatment</td>
<td>Reference</td>
<td>&lt;0.01</td>
<td>Reference</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>1-month post-treatment</td>
<td>–5.73 (–7.47 to –4.10)</td>
<td></td>
<td>–5.78 (–7.47 to –4.10)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Condition</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Controls</td>
<td>Reference</td>
<td>0.17</td>
<td>Reference</td>
<td>0.07</td>
</tr>
<tr>
<td>Intervention</td>
<td>–2.31 (–6.16 to 0.79)</td>
<td></td>
<td>–3.05 (–6.39 to 0.29)</td>
<td></td>
</tr>
<tr>
<td>Tumour site</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral cavity</td>
<td>Reference</td>
<td>&lt;0.05</td>
<td>Reference</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Pharynx</td>
<td>3.45 (–0.67 to 6.63)</td>
<td></td>
<td>3.46 (–0.03 to 6.91)</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Larynx</td>
<td>2.99 (–1.32 to 7.99)</td>
<td>0.17</td>
<td>3.42 (–1.00 to 7.85)</td>
<td>0.13</td>
</tr>
<tr>
<td>Stage</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Reference</td>
<td>&lt;0.05</td>
<td>Reference</td>
<td>0.03</td>
</tr>
<tr>
<td>2</td>
<td>5.57 (–0.61 to 11.89)</td>
<td></td>
<td>6.15 (–0.50 to 11.80)</td>
<td>0.03</td>
</tr>
<tr>
<td>3</td>
<td>–13 (–7.62 to 4.99)</td>
<td>0.96</td>
<td>–3.3 (–7.90 to 5.24)</td>
<td>0.91</td>
</tr>
<tr>
<td>4</td>
<td>1.86 (–3.89 to 7.18)</td>
<td>0.43</td>
<td>2.34 (–4.22 to 7.10)</td>
<td>0.34</td>
</tr>
<tr>
<td>Baseline Depression [PHQ-9]</td>
<td>0.16† (–0.25 to 0.52)</td>
<td>0.37</td>
<td>0.39 (0.12–0.66)</td>
<td>&lt;0.01</td>
</tr>
</tbody>
</table>

*Per unit on PG-SGA: Patient-Generated Subjective Global Assessment.
†Per unit on PHQ-9: Patient Health Questionnaire 9.

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**Table 3.** Linear regression mixed model of nutritional status for high-risk tumour sites only

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Figure 3. Survival curves of controls versus intervention separated by high- and low-risk tumour sites. Cox regression P = 0.03.
esis that the Heads Up intervention would reduce depression.

Similar to nutritional status, depression was affected by the radiotherapy treatment effect [time] as noted above. This is in accordance with other studies, which have consistently reported increases in depression levels from baseline to the end of radiotherapy (Hammerlid et al. 1999; Rose 2001; Kohda et al. 2005; Chen et al. 2009). Depression scores were also related to the number of radiotherapy fractions prescribed. This may be explained by the side effects of radiotherapy such as fatigue and general malaise, confounding the depression scores.

Depression was a secondary study outcome, and the trial was only powered to detect a difference in nutritional status scores, rather than the less prevalent variable of depression. In that context the trend of an average 0.6 points reduction on depression scores in the intervention condition is a positive result and warrants further investigation.

Mortality

Similarly, that 20% of intervention versus 31% of control patients died in the same period post-treatment is noteworthy. The hypothesis that fewer deaths would occur in the intervention condition was a secondary outcome and was not therefore a component of the sample size calculation. Larger studies with longer follow-up periods would be required to assess the true impact of the intervention on mortality.

Subgroup effectiveness

Limiting the analyses to only those HNC patients at nutritional risk due to their tumour site reduced the sample to 69 individuals. Despite this reduction in statistical power the effect of the intervention on nutritional status became stronger, increasing by a factor of 2.5 ($P = 0.07$). This secondary analysis indicates that the intervention may have had some benefit for those patients at high nutritional risk. It is recommended that future studies of nutritional status and its treatment in HNC focus on such patients.

In a secondary analysis among the nutritionally ‘high-risk’ subset of patients, there was a significantly lower risk of mortality among the intervention condition, being half that of the control condition (16% vs. 31%, $P = 0.03$). As this was a non-randomised pilot study, larger randomised studies are required to determine whether an effect on mortality was ‘true’ and replicable among such a sample of nutritionally high-risk patients. At the same time the potential to significantly boost treatment effects via psychological intervention for malnutrition suggests this avenue should be more fully explored.

STRENGTHS AND LIMITATIONS

This study had several strengths. Although the historical control design is not as robust as a randomised controlled trial, it is a stronger pilot study design than a pre-post intervention with the same patients. It was conducted in a working radiotherapy department providing a high level of ecological validity. Finally, the intervention has the potential to be realistically integrated into clinical care without high infrastructure or personnel costs.

The main limitations relate to restricted time and funding. These constraints resulted in a design that utilised historical controls from the previous year to ensure an adequate sample size. The lack of randomisation presents the possibility of confounding factors that may have differentially affected control and intervention conditions.

CONCLUSIONS

This pilot study found a non-significant effect of the Heads Up intervention on nutritional status, depression and mortality across all HNC sites. However, subgroup analyses of patients at high nutritional risk suggested the intervention may improve nutritional status and significantly reduce mortality. The results support the conduct of a larger randomised controlled trial of a psychological intervention among HNC patients likely to be at increased nutritional risk. This would allow for more robust testing of the intervention’s effectiveness. This trial is currently underway by the research team.

CONFLICT OF INTEREST

The authors declare that they have no conflicting interests.

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