A meta-analysis of the efficacy of over-the-counter nicotine replacement


CRD summary
The review compared over-the-counter (OTC) nicotine replacement therapy (NRT) with placebo and with prescription NRT. The authors concluded that OTC was efficacious and resulted in modest quit rates that were similar to those of prescription NRT. The review has some methodological weaknesses, and it is unclear whether the results of the included studies and the synthesis of them can be relied upon.

Authors' objectives
The objectives were to determine whether over-the-counter (OTC) nicotine replacement therapy (NRT) is pharmacologically efficacious and produces abstinence rates similar to those in prescription settings, and to estimate the 6-month abstinence rate.

Searching
MEDLINE and PsycLIT were searched for full papers. Bibliographies of articles were also searched, as were conference abstracts. Pharmaceutical companies and scientists in the field of tobacco or nicotine were also contacted.

Study selection
Study designs of evaluations included in the review
Randomised controlled trials (RCTs) and controlled trials were eligible for inclusion.

Specific interventions included in the review
Studies comparing OTC NRT with placebo or prescription NRT were eligible for inclusion. With the exception of one study that used gum, the included studies used patch NRT. The medication was free in the included placebo-controlled studies.

Participants included in the review
The inclusion criteria for the participants were not specified. By implication, any participants using the intervention of interest were eligible for inclusion.

Outcomes assessed in the review
Studies where the abstinence rates were reported as an outcome were eligible for inclusion. The included studies assessed continuous abstinence, prolonged abstinence and repeated point prevalence. The length of follow-up ranged from 2.5 to 6 months in the placebo-controlled studies, and from 6 to 12 months in the studies comparing OTC with prescription NRT.

How were decisions on the relevance of primary studies made?
The authors did not state how the papers were selected for the review, or how many reviewers performed the selection.

Assessment of study quality
The authors did not state that they assessed validity.

Data extraction
The authors stated that two reviewers independently reviewed the studies and compared results. Details of the intervention were extracted for individual studies. For the placebo-controlled studies, continuous or prolonged abstinence was utilised only when repeated point prevalence was not available. The number of participants abstinent at last follow-up in the treatment and control groups was extracted, and the odds ratio (OR) and 95% confidence interval
(CI) were estimated for the individual studies.

Methods of synthesis
How were the studies combined?
The studies were pooled in a meta-analysis, using a random-effects model when there was evidence of statistical heterogeneity. There was a separate meta-analysis to address each of the three study aims. For the meta-analysis of actual abstinence rates, when more than one outcome was reported the outcomes were given preference in the following order: continuous abstinence, prolonged abstinence, repeated point prevalence.

How were differences between studies investigated?
The chi-squared test was used to investigate statistical heterogeneity between the studies. Some ad hoc sensitivity analyses were also conducted.

Results of the review
Seven RCTs and two controlled trials met the inclusion criteria. Eight trials (n=11,597) were included in the meta-analyses. One RCT, which met the inclusion criteria, was excluded from all the statistical pooling because of the small sample size and the fact that the intervention was not OTC, owing to the amount of contact with participants. A further RCT was excluded from the meta-analysis of actual abstinence rates as the 10-week follow-up was considered too short.

OTC NRT versus OTC placebo (4 RCTs, n=2,290).
OTC NRT was significantly more effective than placebo (OR 2.5, 95% CI 1.8, 3.6). There was no evidence of statistical heterogeneity (P=0.8).

OTC NRT versus prescription NRT (2 RCTs and 2 controlled trials, n=9,307).
At the 6-month follow-up, OTC NRT and prescription NRT produced equivalent rates of abstinence (OR 1.4, 95% CI: 0.6, 3.3). There was evidence of statistical heterogeneity (P=0.01).

Actual abstinence rates with OTC NRT (5 RCTs and 2 controlled trials).
The mean 6-month abstinence rate was 7% (95% CI: 4, 11). There was evidence of statistical heterogeneity (P=0.01).

Authors’ conclusions
OTC NRT is pharmacologically efficacious and produces modest quit rates similar to that seen in real world prescription practice.

CRD commentary
The review question was clear in terms of the intervention, outcomes and study design of interest. However, studies were excluded from some of the analyses although they met the pre-specified inclusion criteria. Two relevant electronic databases were searched, but no details of the search strategy were provided. Unpublished data were sought. Only the data extraction appears to have been carried out in duplicate, thus there is a possibility of error and bias in the study selection process.

Details of the individual studies were available in both tables and the text. Since there was evidence of statistical heterogeneity in two of the meta-analysis, the statistical pooling of these studies was inappropriate. The lack of a quality assessment meant it was not possible to verify if the results of the included studies and, therefore, the authors’ conclusions were reliable. In particular, given the evidence of heterogeneity, the conclusion based on the comparison between OTC NRT and prescription NRT may not be reliable.

Implications of the review for practice and research
The authors did not state any implications for practice or further research.

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