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Oral nicotine pouches for cessation or reduction of use of other tobacco or nicotine products: a Cochrane systematic review

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AIMS

- To evaluate benefits and harms of ONP when used to help people transition away from combustible tobacco use (smoking).
- To evaluate impact of ONP on the prevalence of combustible tobacco use.
- To evaluate benefits and harms of ONP when used to help people transition away from other non-combustible tobacco/commercial nicotine product use.
- To evaluate impact of ONP on prevalence of use of other non-combustible tobacco/commercial nicotine products.

METHODS

- Systematic review of RCTs of ONP use in people using tobacco or other non-combustible tobacco/non-pharmaceutical nicotine products.
- Included studies from 2000 to 13 January 2025. RCTs must report tobacco/nicotine use at 4+ weeks, or biomarkers or adverse events at 1+ weeks.
- Outcomes: **smoking abstinence**, # of people reporting **SAEs**, change in **prevalence** of smoking, **TSNAs**, **COHb**, **metals**, **inflammatory markers**.
- Risk of bias tool: Cochrane RoB 1

What do we know so far about oral nicotine pouches' (ONPs) harm reduction potential?

- **Smoking abstinence** may be slightly higher in people randomized to ONP vs no intervention at 8-week follow-up (low-certainty evidence). Lower abstinence rates in those randomised to ONP compared to e-cigarettes (low-certainty evidence). Higher quit rate in the higher-dose arm in 1 study (n = 30) of higher vs. lower-dose ONP (wide CI).
- No **SAEs** occurred in the 3 studies reporting this outcome. Data were available for comparison ONP vs. minimal control (very low-certainty evidence), and ONP vs. e-cigarettes (low-certainty evidence)
- **TSNA** reported in 1 study of ONP vs. instructions to continue smoking. Lower levels of TSNA with ONP (low-certainty evidence). 2 studies suggest no difference in NNAL levels between higher- and lower-dose ONP (evidence certainty not assessed).
- **COHb** reported in 1 study with ONP vs. instructions to keep smoking; may have lower levels of COHb with ONP (very low-certainty evidence). Very slightly lower levels in higher-dose vs. lower-dose ONP (wide CI) from same study.
- None of the currently-included studies reported on **prevalence**, **inflammatory markers**, **metals**, or **use of other tobacco/nicotine products** (not including cigarettes).
- We identified **10 ongoing studies** which meet our criteria, 2 of which will report on **smoking abstinence at 6+ months** (n=800). We plan to update this review in due course.

INCLUDED STUDIES

We included **4 small studies** (n < 150 for each, total n = 284): Avila (2024), Caldwell (2010), NCT04250727, and Rensch (2023)

- 3 independent
- 1 industry-funded

Risk of bias:

- 3 at high risk of bias
- 1 at unclear risk of bias

- 3 were conducted in the USA, and 1 in New Zealand.
- 2 compared higher- versus lower-nicotine dose ONP.
- 2 compared ONP to instructions to continue smoking as usual.
- 1 each compared ONP to electronic cigarettes (e-cigarettes), snus, and pharmaceutical nicotine replacement therapy (NRT).

All 4 were **RCTs** in people who smoked combustible cigarettes at baseline.

CONCLUSION

More research on the impacts of ONP for cessation or reduction of use of other tobacco or non-pharmaceutical nicotine products and associated health effects is urgently needed.

Future trials should prioritize comparing ONPs to other active interventions, e.g. NRT and e-cigarettes.