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# Osmotic-Controlled Release Methylphenidate for the Treatment of Attention-Deficit/ Hyperactivity Disorder

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Summary of Abstracts

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**About CADTH:** CADTH is an independent, not-for-profit organization responsible for providing Canada's health care decision-makers with objective evidence to help make informed decisions about the optimal use of drugs, medical devices, diagnostics, and procedures in our health care system.

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## Key Message

We found 1 randomized controlled trial about the clinical effectiveness of extended-release methylphenidate with an osmotic-controlled release oral delivery system for the treatment of attention-deficit/hyperactivity disorder in adults.

## Research Question

What is the clinical effectiveness of extended-release methylphenidate with an osmotic-controlled release oral delivery system for the treatment of attention-deficit/hyperactivity disorder in adults?

## Methods

### Literature Search Methods

A limited literature search was conducted by an information specialist on key resources including MEDLINE, Embase, the Cochrane Database of Systematic Reviews, the International HTA Database, and the websites of Canadian and major international health technology agencies, as well as a focused internet search. The search strategy comprised both controlled vocabulary, such as the National Library of Medicine's MeSH (Medical Subject Headings), and keywords. The main search concepts were methylphenidate, osmotic-controlled release oral delivery system (OROS) and attention deficit hyperactivity disorder (ADHD). No filters were applied to limit the retrieval by study type. Where possible, retrieval was limited to the human population. Comments, newspaper articles, editorials, letters, and conference abstracts were excluded. The search was completed on August 15, 2022, and limited to English-language documents published since January 1, 2012. Internet links were provided, where available.

### Selection Criteria and Summary Methods

One reviewer screened literature search results (titles and abstracts) and selected publications according to the inclusion criteria presented in Table 1. Full texts of study publications were not reviewed. The Overall Summary of Findings was based on information available in the abstracts of selected publications.

## Results

One randomized controlled trial was identified about the clinical effectiveness of extended-release methylphenidate with an OROS for the treatment of attention-deficit/hyperactivity disorder in adults.[1] No relevant health technology assessments, systematic reviews, or non-randomized studies were identified.

## Table 1: Selection Criteria

| Criteria | Description |
|---|---|
| **Population** | Adults with ADHD |
| **Intervention** | Extended-release methylphenidate with an osmotic-controlled release oral [delivery] system |
| **Comparator** | Extended-release, controlled-release, or long-acting oral methylphenidate with a different delivery mechanism |
| **Outcomes** | Clinical effectiveness (e.g., behavioural, functional, developmental, or cognitive outcomes; health-related quality of life; changes in severity of ADHD symptoms, time to onset of effectiveness, duration of effectiveness; safety [e.g., adverse events]) |
| **Study designs** | Health technology assessments, systematic reviews, randomized controlled trials, non-randomized studies |

ADHD = attention-deficit/hyperactivity disorder.

Additional references of potential interest that did not meet the inclusion criteria are provided in Appendix 1.

# Overall Summary of Findings

One randomized controlled trial[1] was identified about the clinical effectiveness of extended-release methylphenidate with an OROS for the treatment of attention-deficit/hyperactivity disorder in adults. The authors of this double-blind cross-over study found that satisfaction with efficacy and side effects was greater with the use of extended-release methylphenidate with an OROS (Concerta) compared to the same dose of generic non-OROS extended-release Novo-methylphenidate ER-C.[1] All study participants preferred to continue treatment with Concerta instead of the generic.[1]

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# References

## Health Technology Assessments

No literature identified.

## Systematic Reviews

No literature identified.

## Randomized Controlled Trials

1. Fallu, A., Dabouz, F., Furtado, M., Anand, L., Katzman, M. A. A randomized, double-blind, cross-over, phase IV trial of oros-methylphenidate (CONCERTA(R)) and generic novo-methylphenidate ER-C (NOVO-generic). *Ther Adv Psychopharmacol*. Aug 2016; 6(4): 237-51. PubMed

## Non-Randomized Studies

No literature identified.

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# Appendix 1: References of Potential Interest

## Previous CADTH Reports

Duration of dosage effect for methylphenidate SR and dextroamphetamine SR for patients with attention deficit hyperactivity disorder. *(CADTH rapid response report: summary of abstracts)*. Ottawa (ON): CADTH; 2015: https://www.cadth.ca/sites/default/files/pdf/htis/sep-2015/RB0904_ADHD_Long-Acting_Agents_Final.pdf. Accessed 2022 Aug 17.

## Systematic Reviews

### *Mixed Population – People of Any Age*

Coghill, D., Banaschewski, T., Zuddas, A., Pelaz, A., Gagliano, A., Doepfner, M. Long-acting methylphenidate formulations in the treatment of attention-deficit/hyperactivity disorder: a systematic review of head-to-head studies. *BMC Psychiatry*. Sep 27 2013; 13(): 237. PubMed

## Randomized Controlled Trials

### *Alternative Population - Pediatric*

Lee, S. H., Seo, W. S., Sung, H. M., Choi, T. Y., Kim, S. Y., Choi, S. J., Koo, B. H., Lee, J. H. Effect of methylphenidate on sleep parameters in children with ADHD. *Psychiatry Investig*. Dec 2012; 9(4): 384-90. PubMed

## Non-Randomized Studies

### *Mixed Population – People Aged 6 to 65 Years*

Fife, D., Cepeda, M. S., Baseman, A., Richards, H., Hu, P., Starr, H. L., Sena, A. G. Medication changes after switching from CONCERTA R brand methylphenidate HCl to a generic long-acting formulation: A retrospective database study. *PLoS ONE [Electronic Resource]*. 2018; 13(2): e0193453. PubMed

### *Unclear Population – Adults Not Specified*

Park-Wyllie, L., van Stralen, J., Castillon, G., Sherman, S. E., Almagor, D. Differences in Adverse Event Reporting Rates of Therapeutic Failure Between Two Once-daily Extended-release Methylphenidate Medications in Canada: Analysis of Spontaneous Adverse Event Reporting Databases. *Clin Ther.* Oct 2017; 39(10): 2006-2023. PubMed

Park-Wyllie, L., Van Stralen, J., Almagor, D., Dobson-Belaire, W., Charland, K., Smith, A., Le Lorier, J. Medication Persistence, Duration of Treatment, and Treatment-switching Patterns Among Canadian Patients Taking Once-daily Extended-release Methylphenidate Medications for Attention-Deficit/Hyperactivity Disorder: A Population-based Retrospective Cohort Study. *Clin Ther.* Aug 2016; 38(8): 1789-802. PubMed

### *Alternative Population - Pediatric*

Roh H, Kim B. A Brief Replication Study Comparing Stimulants and Non-Stimulants for Attention-Deficit/Hyperactivity Disorder Treatment with a Focus on the Compliance, Efficacy, and Satisfaction. *Soa Chongsonyon Chongsin Uihak*. 2021;32(1):10-16. PubMed

Cikili Uytun, M., Cetin, F. H., Babadagi, Z. Parent-reported social problems and clinician-evaluated adverse effects may be differentially affected by differing extended release methylphenidate formulations: a prospective, naturalistic study from Turkey. *Psychiatry Clin Psychopharm*. 02 Oct 2019; 29(4)(): 722-729.

van Stralen, J. P. The clinical impact of switching attention deficit hyperactivity disorder patients from OROS(R)-MPH to Novo-MPH ER-C(R): A paediatric practice review. *Paediatr Child Health*. Feb 2013; 18(2): 70-3. PubMed

## Review Articles

Mardomingo-Sanz, M. J. Clinical use of 30: 70 controlled-release methylphenidate in the treatment of attention deficit hyperactivity disorder. *Rev Neurol*. 2012; 55(6)(): 359-369. PubMed

## Additional References

### *Case Series*

Lally, M. D., Kral, M. C., Boan, A. D. Not All Generic Concerta Is Created Equal: Comparison of OROS Versus Non-OROS for the Treatment of ADHD. *Clin Pediatr (Phila)*. Nov 2016; 55(13): 1197-1201. PubMed

### *Drug Class Review*

Drugs used in the management of attention-deficit/hyperactivity disorder in adults. Final consolidated report. Toronto (ON): Ontario Drug Policy Research Network (ODPRN); 2015: https://odprn.ca/wp-content/uploads/2015/12/ADHD-Final-Consolidated-Report_December-21-15.pdf. Accessed 2022 Aug 17.
See “Methylphenidate, osmotic-release oral system” row in Exhibits 5 and 6 (page 25-26); Safety (page 30)